DRAFT FINAL
Butte Priority Soils Operable Unit
Public Health Study
Phase 1

Prepared for:
Butte Silver Bow County and Atlantic Richfield Company
Butte, Montana

Prepared by:
ENVIRON International Corporation
Seattle, Washington

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Preface

This report presents the results of the first phase public health study for the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County. This study was conducted with the oversight of a technical working group that provided direction for the study scope, reviewed the work plan, commented on technical memoranda and webinars as the study was conducted, and reviewed the study report. Working group members are listed below (some members did not participate for the full study period):

- U.S. Environmental Protection Agency – Dr. Susan Griffin and Nikia Greene
- Montana State Department of Environmental Quality – Lisa DeWitt and Joe Griffin
- Agency for Toxic Substances and Disease Registry – Dr. Michelle Watters and Dan Strausbaugh
- Butte Silver Bow Health Department – Dan Powers and Eric Hassler
- Atlantic Richfield Company – Dr. Cord Harris
- Butte Citizen's Advisory Committee – Jay Cornish, Helen Joyce, Dr. Merle Benedict, Dr. John Pullman, Shannon Holland, and Dr. Richard Rossi
- Butte Citizens' Technical Environmental Committee – Dr. Steve Ackerlund

Comments received from the public on a draft work plan were also considered in development of the study.

The study was carried out and this report has been prepared by ENVIRON International Corporation on behalf of the responsible parties, Atlantic Richfield Corporation and Butte Silver Bow County. Funding was provided by Atlantic Richfield. ENVIRON's primary technical team included study director Dr. Rosalind Schoof, Project Manager Dina Johnson, Emma McConnell, Cynthia Van Landingham, Dr. Alexa Gallagher, Alma Feldpausch, Amy Kephart and Dr. Linda Dell.

Public Health Statement

The Draft Final Butte Priority Soils Operable Unit Health Study presents the results of the first phase in a series of public health studies that looks at the effectiveness of the Residential Metals Abatement Program (RMAP) for the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County, Montana.

This Superfund Study Focuses on Assessing Lead Exposures

This health study evaluates blood lead data collected from Butte children from 2003 through 2011, although additional information about RMAP assessments and abatements was also considered. Concentrations of lead in the blood represent lead exposures from all sources (environmental and non-environmental). In this study, blood lead data are evaluated to understand:

- how lead exposures in Butte have changed over this time period,
- how they compare to blood lead levels for areas outside of Butte, and
- what factors in Butte might be contributing to differences in blood lead levels within Butte and between Butte and other reference areas.

The understanding gained is applied toward making recommendations for improving the RMAP program.

The Study Focus on Blood Lead Ensures Consideration of All Sources of Lead Exposure in Butte, Including Superfund-related Sources~~Blood Lead Levels Provide a Measure of Lead Exposure from All Sources~~

Lead exposures of children are a concern in all U.S. communities. Many lead sources and risk factors are linked to higher blood lead levels in children. Sources found in most communities include lead in house paint (from before 1978), lead in plumbing (pipes, brass fittings, and solder), and lead in various products such as toys, lead glazed ceramic dishware, and old mini-blinds. Other sources may include lead related to hobbies such as making fishing sinkers or bullets, and working with stained glass. Higher blood lead levels have been found at homes where batteries are recycled or where parents bring home lead on clothes contaminated at work. Risk factors are characteristics that make a person more likely to have higher blood lead levels. For example, higher blood lead levels are associated with poverty, race, age, and other demographic and social and economic factors. Lead exposures and average blood lead levels have declined dramatically since the 1970s because many lead uses in products have been discontinued; however, individual children may still be found with higher than expected blood lead levels.

In Butte, lead in soil and dust from wastes generated by historical mining operations is also a concern and is the main reason for the Superfund activities. Because there are so many sources of lead exposure in all communities, and because of the variation in blood lead levels with other risk factors, it is difficult to point to any one source contributing to blood lead levels in a group of children. Despite this, the study takes into account the many sources of lead exposure and uses several approaches to evaluate whether~~determine if~~ the RMAP has been

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effective in contributing to reductions~~ing~~ in lead exposures and to identify possible improvements to the RMAP.

~~Butte~~ Blood Lead Levels in Butte Have Declined Dramatically

Blood lead levels in Butte children have dropped dramatically since 2003. Average levels for 2010 of 1.6 µg/dL were less than half of the levels for 2003, of 3.5 µg/dL. The percent of blood lead levels above 10 µg/dL declined by about the same amount. The percent of blood lead levels above 5 µg/dL dropped by an even greater amount, decreasing from 34 percent in 2003 to 10 percent in 2010.

Butte Blood Lead Data Were Compared to Data from a Reference Population Adjusted to Reflect the Butte Community

Butte blood lead levels were compared to blood lead levels for an outside "reference" population to understand how Butte children differ from children in non-mining communities over the same time period. For reference blood lead levels outside of Butte, we used data representative of levels in U.S. children that are collected as part of the National Health and Nutrition Examination Survey (NHANES). When comparing two different populations for blood lead, it is standard scientific process to consider how the characteristics of the two populations compare, how these characteristics might influence blood lead levels, and how this might affect our comparison. In this study, we made adjustments to the NHANES dataset to make the U.S. data more similar to Butte in terms of important risk factors, including poverty status, racial make-up, and the wide-spread presence of older homes.

This study found that average blood lead levels decreased throughout the study period both in Butte and in the NHANES reference population. Average blood lead levels were higher in Butte children compared with the reference children from 2003 through 2008, but during 2009 and 2010 the average levels were the same. This means that blood lead levels were declining faster in Butte than in the reference population. The specific factors causing the higher rate of decline in Butte cannot be conclusively proven~~identified~~ based on this analysis, but the factors could include ongoing RMAP response efforts and reductions in other lead exposure sources.

Blood Lead Levels Were Also Compared Across Butte Neighborhoods

As part of this study, we examined blood lead levels in different Butte neighborhoods to see if there were differences in lead exposures. Blood lead levels decreased rapidly over time in all Butte neighborhoods. However, during the study period children living in neighborhoods in Uptown were found to have higher average blood lead levels than children living in the Flats. The difference between neighborhoods was similar to the difference reported in a 1990 lead exposure study conducted in Butte. The difference between Uptown and the Flats was greater during the summer when outdoor exposures would be greatest. This suggests that for Uptown children, outdoor sources of lead exposures may be more important than for children living in the Flats.

Management of Lead Exposures in Butte

Once a child with an elevated blood lead level is identified in a screening program such as the Women, Infants, and Children program in Butte, the first step is to test the child again to confirm the elevated level. Once a child is confirmed to have an elevated blood lead level, the Butte Silver Bow County (BSB) Health Department follows up with a home visit to interview the family and further test the home to identify the source of lead exposure. Until 2013, 10 micrograms lead per deciliter blood (µg/dL) was used as the trigger for follow up home visits. Starting in 2013, 5.0 µg/dL became the trigger for follow up.

According to BSB Health Department's annual reports of clinical and educational interventions, confirmed blood lead results exceeding 9.9 µg/dL declined from 1.4 percent in 2003-2004 to 0.1 percent in 2010. The Health Department's RMAP program has identified a variety of suspected causes of elevated blood lead levels in Butte, including environmental lead concentrations, toys, dishes, and batteries.

The RMAP assessment and abatement activities conducted within the study area were extensive, but few study area properties include both blood lead and abatement records. For that reason, this study could not directly evaluate if abatements reduced blood lead levels in Butte children. However, review of the RMAP activities and seasonal differences between blood lead levels for children living in Uptown and the Flats suggests that both soil and paint might be contributing to higher outdoor lead exposures in Uptown.

The RMAP Continues to be~~has been~~ an Important Community-Wide Mechanism for Identifying and Reducing Lead Exposures in Butte

Along with other extensive source remediation activities in Butte, the RMAP has been an important community-wide mechanism for identifying and reducing lead exposures from a variety of sources. Based on the findings of this study, our primary recommendation is that the RMAP should be continued. Substantial progress has been made in reducing lead exposures in Butte, but many properties are yet to be assessed. To the extent possible, BSB should build upon community interactions via the RMAP to further promote exposure reduction education and outreach, including exposure reduction related to non-Superfund sources (e.g., house paint). BSB should also continue to seek opportunities to promote community participation in the RMAP, especially in residents of Uptown where increased exposures and risk factors are evident.

We support BSB's 2013 change to follow up when children's blood lead levels are greater than 5 µg/dL. Reducing the level that triggers an assessment should increase the effectiveness of lead abatement efforts in Butte. Because it is often difficult to identify specific causes of moderately elevated blood lead levels (i.e., in the range of 5-10 µg/dL), we also recommend improved procedures for electronic data collection and maintenance to enable increased tracking and follow-up of children with elevated blood lead levels. In addition, we recommend other improvements to the RMAP that could improve future assessments of lead exposures and support periodic re-evaluation of the RMAP's effectiveness.

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Acronyms and Abbreviations

ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
AR	Atlantic Richfield Company
ATSDR	Agency for Toxic Substances and Disease Registry
BLL	Blood Lead Level
BPSOU	Butte Priority Soils Operable Unit
BSB	Butte Silver Bow County
CAC	Butte Citizens' Advisory Committee
CDC	Centers for Disease Control and Prevention
CTEC	Butte Citizens' Technical Environmental Committee
EPA	U.S. Environmental Protection Agency
GM	Geometric Mean
GSD	Geometric Standard Deviation
IWH	Institute for Work and Health
LCL	Lower Confidence Limit
LEAP	Lead Education and Abatement Program
LSMEANS	Least Squares Means
µg/dL	Micrograms lead per deciliter
MDEQ	Montana State Department of Environmental Quality
MDPHHS	Montana Department of Public Health and Human Services
MLE	Maximum Likelihood Estimation
NHANES	National Health and Nutrition Examination Survey
PIR	Poverty Income Ratio
RMAP	Residential Metals Abatement Program
ROS	Regression on order statistics
UCL	Upper Confidence Limit
WIC	Women, Infants, and Children

Glossary of Terms

Accuracy: The degree to which a measurement reflects the true quantitative value of a variable.
Analytical Detection Limit: The threshold below which values cannot be reliably measured.
Analytical Method Sensitivity: The extent to which the analytical method can reliably measure smaller concentrations.
***A Priori* Design**: A design based on deductive reasoning.
Autoregressive Covariance Structure: Measurements farther apart in time are assumed to be less correlated than observations closer in time.
Binning Procedure: Individual bins, defined by a specific set of values for each combination of the variables, such as non-Hispanic whites with a PIR ≤ 1.75 and a house made before 1940. The bins were used in conjunction with estimated Butte data to calculate frequencies for each variable combination, first with Butte data, then NHANES data.
Biomonitoring: A method of assessing individuals' exposures to chemical(s) by measuring quantities of the chemical or its breakdown products in biological specimens such as blood or urine samples.
Capillary Sample: Blood sample obtained by collecting blood from a finger or heel stick.
Chi Square test: Hypothesis test used when the distribution of the test statistic is a chi-square distribution. A chi-square test was used to determine if the slopes of regression models were the same.
Cohort: Individuals with a commonality which comprise a group (Merriam Webster 2013a).
Categorical Variables: Qualitative variables representing grouped data. Examples may include race, income status, or sex (Yale 2013a).
Confidence Interval: An approximate range, estimated from the sample data, within which the unknown parameter is likely to fall (Yale 2013b).
Confidence Limit: Either of the two numbers that specify the endpoints of the confidence interval.
Continuous Variable: Quantitative variables representing data with an infinite number of possible values between two data points.
Correlation: A relationship existing between variables where changes occur together.
Dependent Variable: The response variable which changes based on the independent variable(s).
Exposure: The contact of people with chemicals.
Exposure Medium: The contaminated environmental medium to which an individual is exposed, such as soil, water, sediment and air.
Exposure Pathway: The path a chemical or physical agent takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, an exposure route, and a receptor. If the exposure point differs from the source, a transport/exposure medium (e.g. air) or media (in cases of inter-media transfer) also is included.
Exposure Route: The mechanism by which a contaminant comes in contact with a person (e.g., by ingestion, inhalation, dermal contact).
Extrapolation: To use data in a known interval to make inferences about the values in an unknown interval (Merriam Webster 2013b).
Federal poverty level: The income level by family size used by the U.S. Federal Government to determine poverty status.
Geometric Mean (GM): A measure of central tendency that is typically used when the underlying data is log-normally distributed. The geometric mean is the equivalent of the nth root of the product of n sample values (Merriam Webster 2013c).

Geometric Standard Deviation (GSD): A factor which describes the variation or spread of the values within a distribution which is typically paired with a geometric mean and is usually reported for a lognormal distribution.

Histogram: A graph which represents the frequency distribution of data.

Imputation: A statistical method replacing missing data with substituted values.

Independent Variable: A variable which is used as a predictor or explanatory variable to describe a dependent variable. Independent variables are generally measured or recorded variables.

Interaction Terms: Terms which are added to a model to help determine whether the simultaneous influence of two independent variables on a third (dependent) variable is not additive. For example, sex and age may indicate changes in the dependent variable but if the changes over age are also dependent on the sex (e.g. go up with age in females and down with age in males) then the interaction term is needed.

Least Squares Mean (LSMEANS): Estimated population marginal means based on a group within the model and adjusted for the other covariates in the model (SAS Institute 2013a).

Linear Mixed Model: Allows for multiple patterns of correlation to be modeled and is used to account for repeated measurements and correlated nature of data (Seltman 2013).

Lognormal Distribution: In probability theory and statistics, the lognormal distribution is the probability distribution function of random variables whose logarithms are normally distributed.

Log Transformed data: Data for which the logarithm was taken of each observation.

Maximum Likelihood Estimation (MLE): A procedure of finding one or more parameters of a function such that the known likelihood distribution for the function is at a maximum. This procedure is a standard method used in statistics for parameter estimation and inference statistics (Helsel 2005).

Mean: The average value of a set of numbers.

Media: Specific environmental components—air, water, soil—which are the subject of regulatory concern and activities.

Median: The middle value in an ordered set of numbers.

Multivariable Statistical Model: Model that contains more than one independent variable and examines each variable's influence on the dependent variable (e.g., blood lead level) after adjusting for the other variables in the model.

Natural Log: A logarithm with the base e.

Non-detect: A number below the lowest value which can be reliably measured.

Normal (Gaussian) Distribution: A distribution in which probability density function of random observations is symmetric around the mean and forms a bell-shaped curve.

Percentile: A value below which a specified percentage of observations within a population of data fall (e.g., 95^{th} percentile).

Poverty Income Ration (PIR): The total family income divided by the federal poverty threshold specific to family size, year and state of residence.

Precision: A measure of the closeness of agreement among individual measurements.

P Value: Expression of the level of statistical significance of a statistical result and the likelihood it is not a product of chance (IWH 2005).

Regression on Order Statistics (ROS): A method of determining possible values for left-censored data (non-detects) in a data set. This method uses a regression line that is fit to the normal scores of the order statistics for the uncensored observations (the detected values) and then fills in values extrapolated from the straight line for the observations below the detection limit.

Sensitivity Analysis: Assesses the influence of factors or assumptions, such as missing data or method of analysis, on the study conclusions (Thabane et al. 2013).

Statistically Significant: When observed differences between groups are determined to not be attributable to chance (IWH 2005).

Statistical Power: The probability that a statistical test will reject the null hypothesis when the null hypothesis is false (IWH 2005).

Surrogate Indicator: A substance or compound which can suggest the presence of another.

T-Test: A test which can measure the difference between two groups' mean responses (SAS Institute 2013b).

Univariate Model: Model that contains only one independent variable and examines that variable's influence on the dependent variable (e.g., blood lead level).

Venous Sample: Blood sample obtained from the vein via venipuncture.

Weighting Factor: Estimated value which modifies the influence of a record on the overall fit of the parameters of a model to the data.

Executive Summary

A series of public health studies are called for in addressing the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County, Montana. Remediation activities in BPSOU have included a Residential Metals Abatement Program (RMAP) administered by Butte Silver Bow County (BSB) to address potential exposures to lead, arsenic, and mercury in residential areas of Butte. The primary study objective to be addressed by the Superfund health study is the review and evaluation of available RMAP data that have been collected to date in order to objectively document the efficacy of the RMAP and identify any areas where improvement to activities conducted via the RMAP may be needed. To date, lead has been the primary focus of activities conducted under the RMAP.

This report presents the result of the first Superfund health study. As part of the scoping process for the Superfund health study, "non-Superfund" health concerns were also identified by residents. The non-Superfund studies will be reported separately.

Blood Lead Data are Used to Assess Lead Exposures

Consistent with the RMAP focus, this phase of the Butte health study focuses on lead. For many years, the BSB Health Department has collected blood lead data that could be used to support an assessment of Butte lead exposures. Concentrations of lead in the blood provide a reliable measure of lead exposures from all sources (environmental and non-environmental).

Many sources and risk factors are associated with higher blood lead levels in children. In addition to lead from historical mining operations, sources include lead in paint, plumbing, and various consumer products such as toys, lead glazed ceramic dishware, and old mini-blinds, as well as lead associated with hobbies such as making fishing sinkers or bullets, and stained glass. Elevated lead blood lead levels have been found at homes where batteries are recycled or where parents bring home lead on clothes contaminated at work. Higher blood lead levels are also associated with poverty and other demographic and socioeconomic factors. Lead exposures and blood lead levels have declined dramatically since the 1970s as many lead uses have been discontinued; however, individual children may still be found with elevated levels.

The Study Evaluated Two Primary Lines of Evidence

The study was focused on evaluating two primary lines of evidence. For the first, we compared Butte blood lead levels with those in other parts of the U.S. to understand whether lead exposures in Butte are high relative to other areas while accounting for some other common factors that might influence blood lead levels in both areas. For the second, we evaluated whether lead exposures are different in different Butte neighborhoods to better understand some of the factors within Butte that may still be contributing to higher blood lead levels in some residents. The study focused on children from 12 to 60 months of age because children in this age range typically have higher blood lead levels and are more sensitive to the effects of lead compared with older people. Butte blood lead records for nearly 3,000 children tested from 2003 through 2010 were considered in the study along with additional records collected in 2011 and supplemental information about RMAP assessments and abatements that have been conducted.

Blood lead levels in Butte children have declined dramatically since 2003. Average values for 2010 were less than half of the values for 2003, with geometric means having declined from 3.5 µg/dL in 2003 to 1.6 µg/dL in 2010. The percent of blood lead levels above 10.0 µg/dL declined by a similar magnitude, while the percent of blood lead levels above 5 µg/dL declined by an even greater margin, decreasing from 33.6 percent on 2003 to 9.5 percent in 2010.

Comparison of Butte Blood Lead Levels with a U.S. Reference Population

Blood lead data representative of levels in U.S. children are collected as part of the National Health and Nutrition Examination Survey (NHANES). These data were used to develop a reference dataset for this study, adjusting the NHANES dataset so that known risk factors for lead exposures were matched to conditions present in Butte. This included adjustments to match the distribution of house age[1], poverty levels and races in the Butte study population. Butte blood lead data were then compared to the NHANES reference dataset to assess if Butte children are affected by Superfund sources in addition to lead exposure sources present in non-Superfund communities.

The NHANES is conducted over two year periods. This study examined four two-year periods for which both NHANES and Butte data were available: 2003-2004, 2005-2006, 2007-2008 and 2009-2010. Average blood lead levels were found to be higher in Butte children compared with the NHANES reference dataset during the first three test periods, i.e., during 2003-2004, 2005-2006, and 2007-2008. This difference disappeared for Butte children tested during 2009-2010. For that time period there was not a statistically significant difference between blood lead levels in Butte children and the NHANES reference dataset (see Figure ES1).

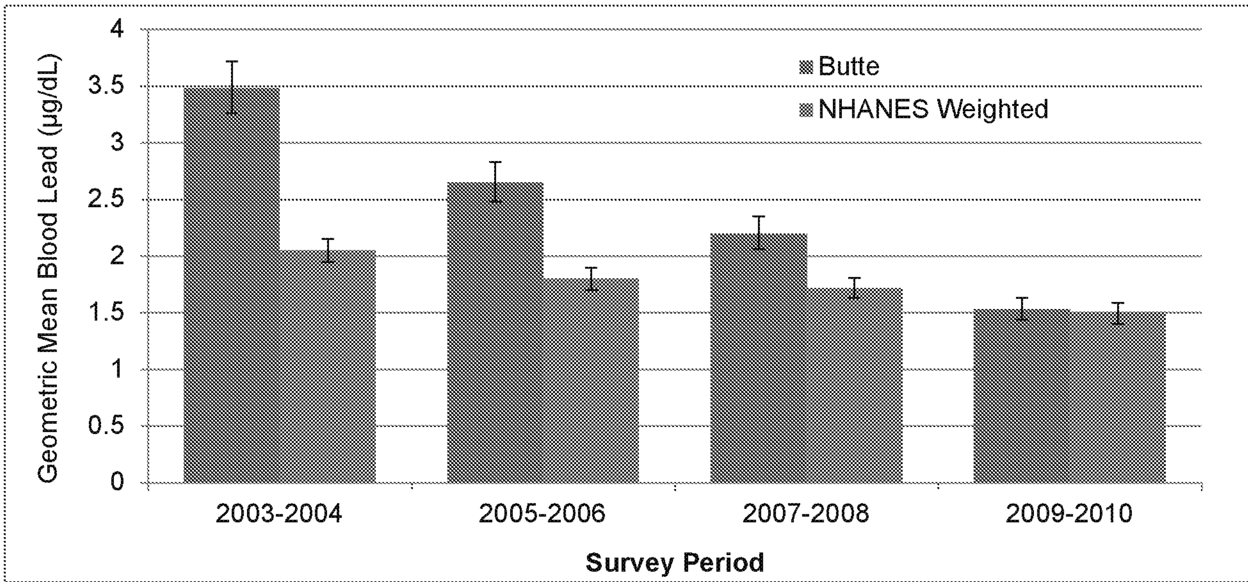

Figure ES1: Modeled Geometric Mean Blood Lead Levels for Butte Compared to the Adjusted NHANES Data by Test Year with 95% Confidence Intervals

[1] Throughout the study, the term "house" refers to any residential dwelling, including single family homes as well as multifamily housing complexes and "house age" refers to the range of years within which the house was built.

The lack of a significant difference between Butte and the NHANES reference dataset during the 2009-2010 reflects a greater rate of decline in Butte blood lead levels during the prior time periods. The specific factors causing the higher rate of decline in Butte cannot be determined based on this analysis, but such factors could include ongoing RMAP response efforts, as well as reductions in other lead exposure sources or risk factors.

As described by the Centers for Disease Prevention and Control, "persistent differences between the mean BLLs of different racial/ethnic and income groups can be traced to differences in housing quality, environmental conditions, nutrition, and other factors." (CDC 2013b) To the extent that we were not able to adjust the reference population for all lead exposure risk factors present in Butte, we cannot specify the causes of differences between Butte and reference population blood lead levels in earlier study periods.

Butte Neighborhood Blood Lead Level Comparison

The second part of this study examined blood lead levels in different Butte neighborhoods to see if there were differences in lead exposures. A study conducted during 1990 found that overall blood lead levels of Butte children were not elevated when compared to national blood lead levels; however, the study did find that blood lead levels were higher in the Uptown area of Butte compared with some neighborhoods in the Flats. In this study the 2003-2010 Butte blood lead data were also examined to assess any differences by neighborhood. A statistical model was used to account for differences in known lead exposure risk factors, specifically house age, child age and gender, and test season, and then the neighborhood blood lead levels were compared.

During all four study periods (i.e., 2003-2004, 2005-2006, 2007-2008, and 2009-2010) children living in neighborhoods in Uptown were found to have higher average blood lead levels than children living in the Flats. The magnitude of the neighborhood differences was similar to the difference observed in the 1990 study (Figure ES2).

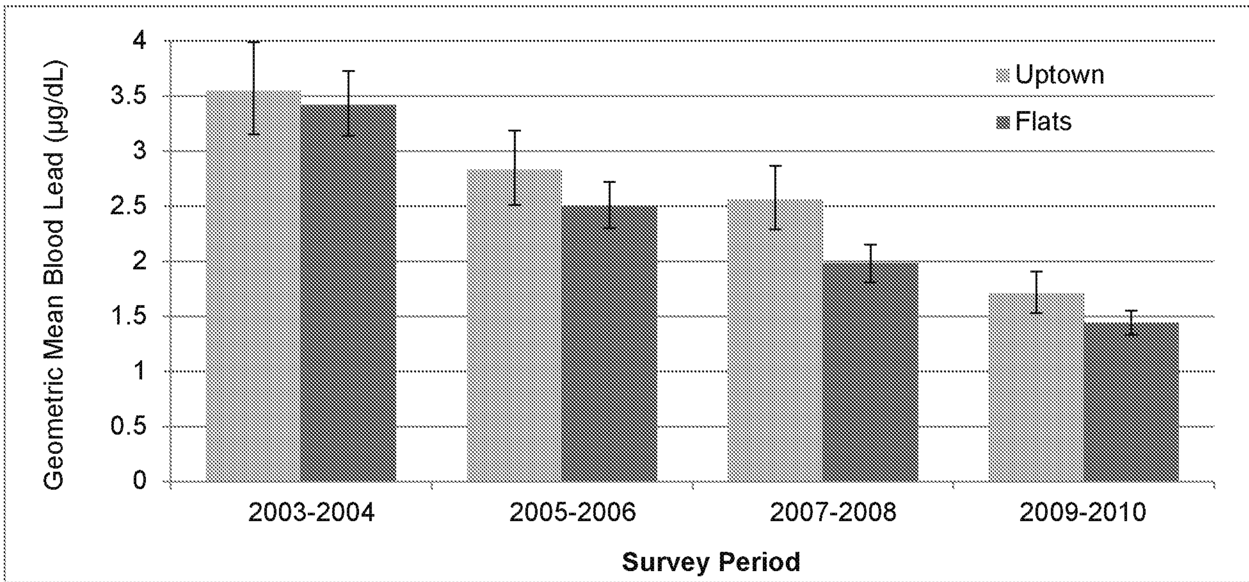

Figure ES2: Modeled Geometric Mean Blood Lead Levels for Uptown vs. the Flats by Test Year with 95% Confidence Intervals

The difference between Uptown and the Flats was greater during the summer when outdoor exposures would be greatest. This suggests that for Uptown children, outdoor sources of lead exposures may be more important than for children living in the Flats.

Management of Lead Exposures in Butte

During the 2003 through 2010 study period, the Centers for Disease Control and Prevention (CDC) recommended 10 micrograms lead per deciliter blood (µg/dL) as a blood lead "level of concern" when based on a confirmed venous blood draw. This level of concern was used as a risk management tool by the BSB Health Department to identify children who might have elevated lead exposures so that actions to reduce such exposures could be initiated. Children with confirmed venous blood lead results exceeding 9.9 µg/dL were referred for case management, including home visits when appropriate, intensive education for the family, environmental investigation and follow up blood lead testing.

According to BSB Health Department's annual reports of clinical and educational interventions, screening blood lead results confirmed to exceed 9.9 µg/dL declined from 1.4 percent in 2003-2004 to 0.1 percent in 2010. The Health Department identified a variety of suspected causes of elevated blood lead levels in these children. Starting in 2013, home visits were scheduled for all children with blood lead levels of 5.0 µg/dL or higher, consistent with a new blood lead reference level issued by the CDC.

The RMAP assessment and abatement activities conducted within the study area were extensive, but few study area properties include both blood lead and abatement records. For that reason, this study could not directly assess if abatements reduced blood lead levels in Butte children. However, most RMAP activities occurred in the Uptown neighborhoods with similar frequency of interior/exterior house paint and yard soil abatements. In the Flats, the number of paint abatements exceeds yard soil abatements. Based on this finding, review of the RMAP activities suggests that both soil and paint might be contributing to higher lead exposures in Uptown, while in the Flats, the relative contribution of soil lead to overall exposures is likely lower.

Recommendations

Coupled with other extensive source remediation activities in Butte, the RMAP has been an important community-wide mechanism for identifying and reducing lead exposures from a variety of sources. Based on the findings of this study, our primary recommendation is that the RMAP should be continued. Substantial progress has been made in reducing lead exposures in Butte, but many properties are yet to be assessed. To the extent possible, BSB should build upon community interactions via the RMAP to further promote exposure reduction education and outreach, including exposure reduction related to non-Superfund sources (i.e., house paint). BSB should also continue to seek opportunities to promote community participation in the RMAP, particularly among residents of Uptown where increased exposures and risk factors are evident.

In 2013, BSB changed the trigger for follow up of children's blood lead levels to greater than 5 µg/dL. Reducing the level that triggers an assessment should increase the effectiveness of lead abatement efforts in Butte. It should be noted that it is often difficult to identify specific causes of moderately elevated blood lead levels (i.e., in the range of 5-10 µg/dL), and for that reason, we also recommend improved procedures for electronic data collection and maintenance to facilitate increased tracking and follow-up of children with elevated blood lead levels.

Several other recommendations relate to collection of blood lead data that could be used in the future to assess the effectiveness of continued efforts to reduce lead exposures. We recommend restoring blood lead testing procedures that produce reliable results at a detection limit of 1 µg/dL or lower (a new method began in late 2011 has a detection limit too high to calculate mean values for blood lead levels). We also recommend improving the consistency with which complete blood lead records are collected, regardless of blood lead testing referral source (i.e., RMAP vs. WIC vs. pediatrician). To the extent legally possible, BSB should also consider collection of additional information from blood lead tested individuals that will improve interpretation of lead exposure trends going forward (e.g., race, maternal education, household income level). These changes would allow for an update of this study in the future to assess RMAP effectiveness.

1 Introduction

This document presents the results of the first phase in a series of public health studies for the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County, Montana (hereafter, the "Butte health study"). This phase of the Butte health study focuses on analyses of Butte Silver Bow (BSB) County blood lead data compiled from 2003 through 2010 to determine if lead exposures by residents differ between the study area and a comparable population or across neighborhoods within the study area. These primary analyses are supplemented by consideration of available Butte environmental data as well as other blood lead data for communities outside of Butte. Collectively, these analyses are designed to support an evaluation of the effectiveness of ongoing remediation and residential metals abatement efforts in the study area that have occurred since the early 1990s. Based on these analyses, recommendations are included regarding potential improvements to current remediation/abatement approaches.

1.1 Study Background and Development Process

This health study has been conducted in accordance with the U.S. Environmental Protection Agency (EPA)-approved Butte health study work plan dated May 2013 (ENVIRON 2013a). The primary study objective to be addressed by the health study is the review and evaluation of available Residential Metals Abatement Program (RMAP) data that have been collected to date in order to objectively document the efficacy of the RMAP and identify any areas where improvement to activities conducted via the RMAP may be needed. To address the study objective, the approved study plan proposed to focus on analyses of the more than ten years of blood lead data compiled by BSB to assess blood lead levels (BLLs) in Butte children. More specifically, the plan called for examination of the blood lead data to assess whether changes in community-wide exposures are evident based on the following lines of evidence:

- The distribution of BLLs in the Butte community and in a reference population are similar over the same period evaluated.

  and

- Statistically significant differences in BLLs across neighborhoods within the Butte community, measured in conjunction with the RMAP, are reduced relative to differences documented pre-RMAP in BLLs across Butte neighborhoods.

As discussed in the EPA-approved work plan, if the lines of evidence support a finding that improvements to the RMAP are necessary to identify and mitigate potentially harmful exposures to sources of lead, arsenic, and mercury in the Butte community, then response actions appropriate to addressing identified RMAP deficiencies would be proposed for further investigation.

The focus of this study phase was developed after consideration of a range of possible studies and concerns expressed by Butte citizens during community meetings conducted early in the process. The final plan for this study was developed with technical input and collaboration with representatives from EPA, the Montana State Department of Environmental Quality (MDEQ), BSB Health Department, the Agency for Toxic Substances and Disease Registry (ATSDR), Atlantic Richfield (AR), and the Butte Citizens' Technical Environmental Committee (CTEC).[2] Public comments received during the draft study work plan public comment period, which occurred from late 2012 through early 2013, were also considered in finalizing the study work plan for this study.

Health studies for communities affected by environmental contaminants can start either with evaluation of exposures or of disease rates. If a study beginning with evaluation of exposures reported elevated exposures, the next step would be to recommend ways to reduce exposures, and the results could also guide design of future studies of disease rates to focus on diseases possibly related to those specific chemical exposures. Other studies looking broadly at disease rates may be a useful supplement to exposure studies, but in most cases such studies are not as sensitive as focused exposure studies. Both kinds of studies were considered prior to developing the study summarized in this report, which focuses on the evaluation of available lead exposure data in Butte. Additionally, a study of cancer incidence and mortality was also requested and subsequently conducted by the Montana Department of Public Health and Human Services (MDPHHS) early in the study planning process. The MDPHHS study was conducted independently. A summary of the MDPHHS study that was presented in the approved work plan (ENVIRON 2013a) is reproduced in Appendix A to this study report along with a copy of the publically-available MDPHHS study (MDPHHS 2012).

Once the focus of the study was approved in the final work plan, execution of the study design was sequenced to present information on key development steps to the study Working Group members from EPA, MDEQ, ATSDR, CTEC, BSB, and AR. Members of the Butte Citizens' Advisory Committee (CAC) were also invited to each Working Group meeting. The CAC is comprised of technically qualified community members who were appointed by the BSB Board of Health early in the work plan development process to provide input to the study design and implementation process. A summary of the topics presented at each Working Group meeting is provided below along with interim study deliverables for which Working Group review and comments were sought prior to the submission of each deliverable to EPA for approval in consultation with MDEQ:

- Working Group Meeting #1 web-based presentation and conference call on July 17, 2013 included:
  - Proposed preliminary delineation of neighborhoods (study subareas) within the Butte study area to support evaluation of BLL differences across Butte over the study time period.
  - Review of key factors to consider in selecting a reference blood lead dataset for comparison to the Butte blood lead data.
  - Proposed selection of the National Health and Nutrition Examination Survey (NHANES) blood lead dataset as the reference dataset for use in the study and preliminary

[2] Participation by the CTEC representative began during the public comment period for the draft study work plan, after the study focus was selected.

discussion of some of the weighting adjustments that might be needed to ensure the national data were comparable to the Butte data.

- Review of the Butte blood lead database development and documentation process.

- Technical Memorandum Deliverable - Proposed Reference Blood Lead Data for Use in the Butte Health Study (ENVIRON 2013b):
  - Submitted for EPA approval, in consultation with MDEQ, on August 20, 2013.
  - Approved by EPA, in consultation with MDEQ, on September 3, 2013.
- Working Group Meeting #2 web-based presentation and conference call on October 30, 2013 included:
  - Proposed statistical approaches for use in addressing the study's two primary study questions.
- Working Group Meeting #3 web-based presentation and conference call on December 5, 2013 included:
  - Review of preliminary study results for each of the study's two primary study questions.
- Working Group Meeting #4 conference call on February 5, 2014 included:
  - Review of comments received from Working Group and CAC review of internal draft study report and discussion of comment resolution and associated draft report revisions to be made prior to formal submittal of revised draft report to EPA in consultation with MDEQ.
- Draft Final Study Report Deliverable:
  - Submitted for EPA approval, in consultation with MDEQ, on February 28, 2014.

The Working Group will also participate in planning for the draft report public meeting, review and response to public comments on the draft report, and development of the draft final report for submittal to EPA for review and approval, in consultation with MDEQ.

1.2 Focus on Butte Lead Exposure Data

EPA's goal in managing Superfund sites is to ensure that chemical exposures are kept low enough to prevent increases in disease rates. EPA conducts assessments that predict potential risks for people expected to be most highly exposed and most susceptible to adverse health effects. EPA then sets cleanup goals expected to protect sensitive members of the population. For BPSOU, EPA reviewed data for multiple chemicals in soil and dust and determined that the primary chemicals of concern were lead, arsenic and mercury, and set cleanup levels for all three chemicals. BPSOU cleanup efforts for arsenic, lead, and mercury have been underway for more than 20 years. AR has conducted much of the cleanup outside of residential areas, and BSB has been leading residential yard and home metals abatement efforts.

The current RMAP and its predecessor program led by BSB have also included a biomonitoring program in which over 3,000 blood lead samples have been collected from Butte children over the past ten years. Arsenic and mercury biomonitoring have also been offered under this program since 2010 but only when environmental sample concentrations in soil or dust[3] are high enough to warrant such testing. Because the environmental concentrations were seldom high enough to offer such testing, there are no comparable arsenic and mercury biomonitoring data. Additionally, RMAP data collected through May 2013 suggest that elevated lead is more prevalent in Butte than elevated arsenic and mercury. For instance, 89 percent of all properties with at least one lead and/or arsenic sample result that exceeded a yard soil action level were due to lead alone. For homes where an indoor dust action level was exceeded (including attics or basements), 44 percent were due to lead alone while less than 1 percent was due to arsenic alone. In all of the RMAP soil and dust samples, there were only two properties with yards exceeding the mercury action level and six with indoor dust exceeding the action level. All of those properties also had lead exceedances.

Using the available blood lead data to assess exposures in Butte is desirable because BLLs provide a direct and relatively stable measure of all sources of lead exposures a child may have, including lead exposures from soil, dust, water, air, food, paint, and consumer products.[4] Furthermore, BLLs are measured each year in thousands of U.S. children, making it possible to compare Butte levels with BLLs for children outside of Butte.

1.3 Overall Study Approach

As discussed in the approved work plan for this study, the principal question to be addressed by this study is:

> Do environmental and biomonitoring data collected for the RMAP support a finding that the program has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community and, if not, what actions can be taken to improve the efficacy of the RMAP?

As described above, the study design focuses on lead. The study design includes statistical examination of two lines of evidence to evaluate the principal study question. The first line of evidence looks at whether the distributions of BLLs in the Butte community and in a reference population are similar over the same period evaluated. The second line of evidence looks at whether statistically significant differences in BLLs across Butte neighborhoods, measured in conjunction with the RMAP, are reduced relative to differences documented in pre-RMAP BLLs across Butte neighborhoods.

A multi-step process is used to develop a separate multivariable statistical model to address each line of evidence. Supplemental analyses of available environmental and other data augment interpretation of model outputs and help guide identification of a range of possible recommendations or response actions for further consideration to ensure ongoing effectiveness of the RMAP.

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[3] Dust includes indoor (living space) dust and attic dust, when exposure pathways for attic dust are identified.
[4] Blood lead measurements do not distinguish how much individual sources of lead exposure contribute to the overall exposure.

1.4 Report Organization

This report provides a detailed summary of all of the data, methods, analyses and results associated with addressing the principal study question and its dual lines of evidence. To the extent that information relied on this study was included in the approved study work plan (ENVIRON 2013a) or in the approved technical memorandum for selection of the study reference blood lead (ENVIRON 2013b), it has been referenced throughout this report, but may or may not be re-summarized herein. Deviations from the procedures stated in the work plan and this report are provided in Appendix B. Organization of the remainder of this report is as follows:

- Section 2 – The Butte blood lead database is described along with data refinements and treatments applied to the data to prepare it for use in the study's statistical models.
- Section 3 – Factors influencing BLLs are described.
- Section 4 – Development of the statistical model to assess the first line of evidence (comparison to NHANES) is presented including further data adjustments, assumptions, methods, results, and conclusions.
- Section 5 –Development of the statistical model to assess the second line of evidence (differences in BLLs across Butte neighborhoods) is presented including further data adjustments, assumptions, methods, results, and conclusions.
- Section 6 – Supplemental analyses conducted to augment interpretation of the findings from both primary study analyses are described and results presented.
- Section 7 – Overall study conclusions are summarized and discussed including preliminary identification of proposed response actions or other recommendations for improved effectiveness of the RMAP toward reducing Butte metals exposures.
- Section 8 – References cited in the study are listed.

2 Butte Blood Lead Data

As described in the approved work plan (ENVIRON 2013a), blood lead data used in this study originated from BSB Health Department blood lead testing records. The majority of the blood lead records came from patients recruited for regular blood lead testing through the Women, Infants, and Children (WIC) program in Butte.[5]

In June 2012, blood lead data from hard copy records maintained by the BSB Health Department were compiled by a team of individuals authorized by the BSB Health Department to access the confidential information. Compilation of the BSB Health Department blood lead testing records resulted in a blood lead database containing 7,278 blood lead records with collection dates ranging from 1992 to 2012, although only very limited data were available prior to 2002. Entry of each hardcopy record into the electronic database was double-checked by an individual from the compilation team who had not entered the original data.

Most, but not all records compiled included a patient's blood lead result, test date, age at test date, gender, address, and test method. Individuals represented in the database included infants, children, and adults with age at time of testing ranging from 1 month to 70 years. The database included results from both capillary (finger or heel stick) and venous (whole blood) sample collection methods. The majority of blood lead samples had been submitted for laboratory analysis with a detection limit of 1.0 µg/dL; however, in December 2011, the BSB Health Department began using a portable lead analyzer, LeadCare II, with a detection limit of 3.3 µg/dL. Use of the LeadCare II analyzer was initiated to allow for more immediate follow-up when blood lead results are elevated. Prior to March 2013, WIC was referring its clients for venous confirmation sampling if LeadCare II results exceeded 9.9 µg/dL. Since then, confirmations are recommended whenever a LeadCare II result exceeds 5.0 µg/dL, the level CDC currently recommends for identifying children with blood lead levels that are much higher than most children's levels. The CDC (2012) states: "This new level is based on the U.S. population of children ages 1-5 years who are in the highest 2.5% of children when tested for lead in their blood."

The BSB Health Department records did not include house age[6] information for each individual tested. When it could be located, this information was later added to the database from land survey and property tax data (See Appendix C). Additionally, using the address data, all records were mapped to a census tract where the tested individual's residence was located, and these census tract assignments were also added to the database.

2.1 Refinement of the Blood Lead Database to Support this Study

Refinement of the full blood lead database compiled from BSB records and augmented by property age and census tract assignments was necessary to ensure a complete set of records for use in the health study. Figure 1 depicts the process for blood lead record refinement. Initial

[5] The qualification for WIC is 175% of the federal poverty level or below. However, county blood lead records include those from WIC clients as well as from individuals referred via the RMAP and local physicians.
[6] Throughout the study, the term "house" refers to any residential dwelling, including single family homes as well as multifamily housing complexes and "house age" refers to the range of years within which the house was built.

database refinement excluded records that lacked one or more of the following key pieces of information: test result, participant birthdate, a physical street address for participant's residence at time of testing (i.e., P.O. Box was not sufficient), and participant gender. The remaining 6,608 "complete" records were then further refined as follows:

- Records were excluded for individuals tested at ages that fell outside of the study age range of 12 to 60 months.
- Records obtained by use of the LeadCare II device were excluded as these lacked sufficient sensitivity and precision to support study objectives.
- Records were excluded if they were associated with addresses that were outside of the Butte study area delineated by Silver Bow County Census Tracts 1 through 8.

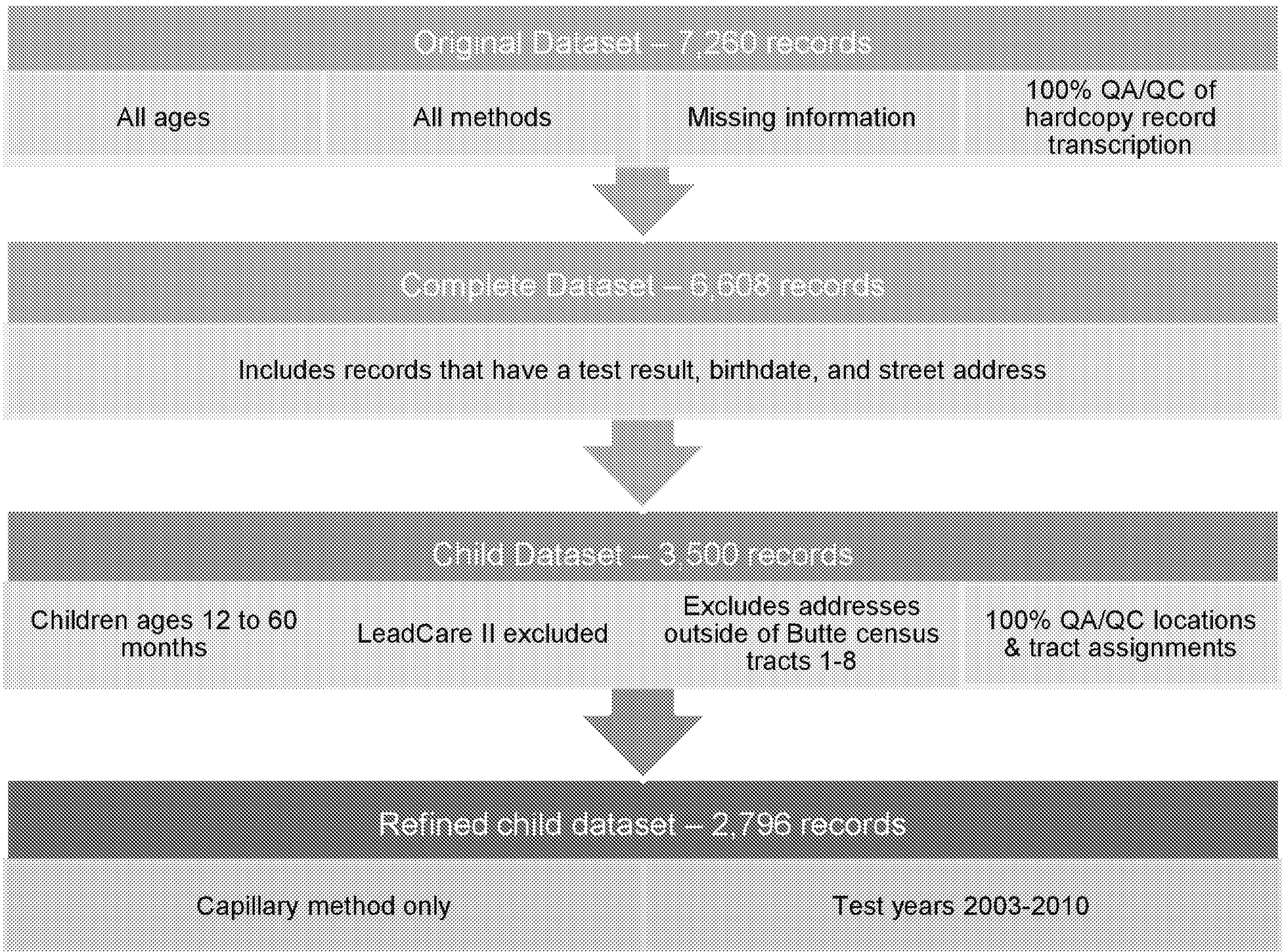

Figure 1: Outline of the Data Refinement Process

Completion of these refinements resulted in a base dataset including 3,500 records that corresponded to the 2002 through 2011 time period. Of these records, most were obtained via capillary sample collection; only 108 were based on venous sample collection. Venous samples in this dataset were most likely collected as confirmatory samples following elevated blood lead results from less invasive, capillary sampling. However, linkages of the capillary and venous data in the BSB records were not evident in most cases. To avoid potential bias in the study analyses that might be introduced by counting both capillary and confirmatory venous results as independent measures for a given individual, all venous records were excluded from the refined child dataset. While studies of simultaneous collection of venous and capillary blood lead samples have shown good correlation, a key concern with the use of finger stick sample collection versus venous sample collection is the potential for external contamination of the blood sample from lead on the skin which is very difficult to remove completely (ACCLPP 2012). Consequently, data collected by finger stick is likely to be biased high compared with data collected by venous samples; in other words, blood lead concentrations determined from capillary samples might be higher than those based on venous samples. Exclusion of venous data may include cases where a capillary result was reported as elevated and venous data confirmed that the blood lead was actually not elevated. This also might result in overestimation of blood lead levels for the Butte study participants. However, the potential impact of these potential~~is~~ sources of bias in the overall study analyses is overestimation of blood lead levels in Butte, which is a conservative outcome and more acceptable~~was determined to be more acceptable~~ than including~~sion of~~ the venous data without more details as to if or how each result relates to other specific capillary results.

Following these refinements, a total of 3,392 records remained in the dataset. Records supporting model development to address the two primary study questions were further limited to test years 2003 through 2010. This ensured alignment with available test years in the NHANES dataset and provided sufficient sample sizes for comparison of trends over time and across neighborhoods in the Butte dataset. Data for 2002 included only 125 records compared to 300 or more records for each of the other years. Data for 2011, which consisted of 470 records from January through early December, were not included in the main statistical models, but were retained in the database and used for supplemental study analyses. With the exclusion of the 2011 data, a total of 2,796 records remained in the refined child dataset.[7]

2.2 Specific Data Treatments Applied to the Study Data

Following refinement of the Butte blood lead database for use in the study, specific data treatments were evaluated and applied as appropriate to support statistical evaluation of the data in addressing each of the primary study questions. These are discussed below.

2.2.1 Log-transformation of Blood Lead Data

Initial evaluation of blood lead data for the refined dataset used histograms to understand how the blood lead results were distributed for the study population. Data were plotted first examining all of the records together and then grouping the records into four 2-year periods. Additional plots were examined based on child gender and child test age groups (12-35 months, 36-50 months). Based on P-P plots, histograms (example shown in Figure 2), and examining values for "skewness", the data fit a lognormal distribution. In other words, the majority of the data fall on the low end of the distribution and very few data points fall in on the highest end of the distribution. This distribution is common for blood lead data with the majority of people

[7] A single capillary blood lead result reported in 2008 with a detection limit different from the other records (3 µg/dL rather than 1 µg/dL) was removed from the refined child dataset to result in 2,796 records.

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having very low BLLs and fewer people having levels that are several times higher. Most statistical tests require data to fit a "normal" or Gaussian distribution for valid application. In order to transform the data from the lognormal distribution to the normal distribution, the natural log of each record must be calculated. This transformation was performed on the Butte dataset in order to make the data suitable for use in common statistical tests.

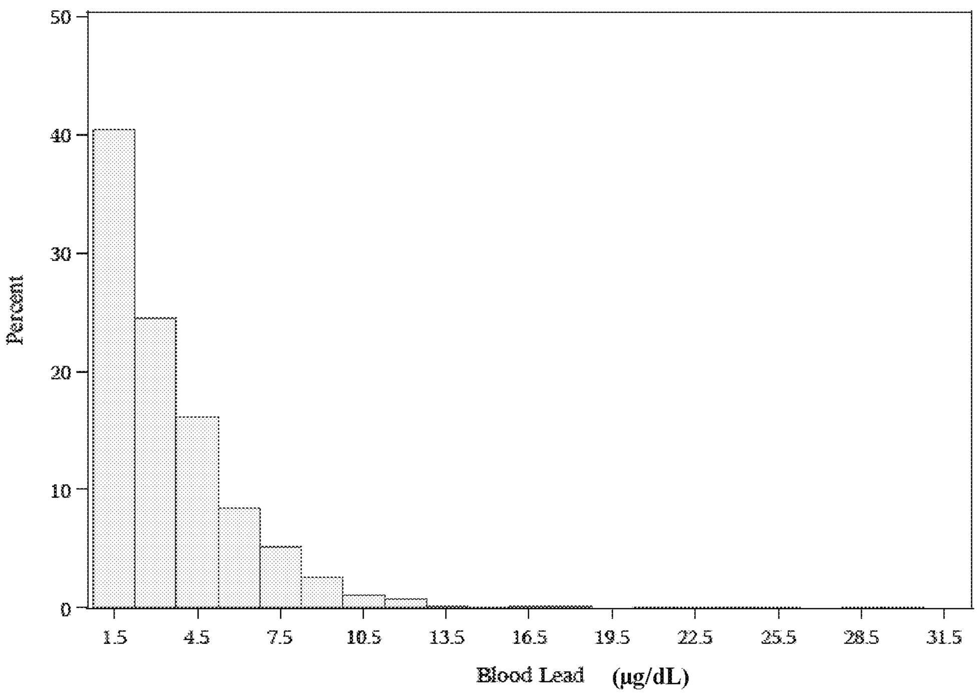


Figure 2: Blood Lead Distribution for Butte (2003-2010)

2.2.2 Handling Non-Detect Blood Lead Data

When a blood lead result is reported as "not-detected" or "non-detect," the blood lead concentration is known to be below the detection limit for the sample analysis, though the exact concentration cannot be determined. The 2,796 blood lead records in the refined child dataset have a detection limit of 1.0 µg/dL and 364 were reported below the detection limit, with a higher proportion of non-detected values in the more recently collected data.

There are a number of accepted options for adjusting the non-detects for use in statistical analysis, including: no action (where all non-detects are replaced with the detection limit); replacement with zero; replacement with half the detection limit; replacement with detection limit divided by the square root of two; maximum likelihood estimation (MLE); extrapolation; and imputation. Replacing the non-detects with the detection limit will cause the results to be higher than they actually are, while replacing the non-detects with zero will produce artificially low values. The other options may come closer to approximating the true values below the detection limit, and the more sophisticated methods of MLE, extrapolation, and imputation are ideal when the computational expertise exists to use them.

To assess the effect of different data treatment options on the Butte data, the following four treatment methods were compared:

- Replacing the Butte non-detects with the detection limit.
- Replacing the non-detects with the detection limit divided by the square root of two.
- Imputing the non-detects with values from a known blood lead distribution.
- Extrapolating the non-detects from the known values in the Butte dataset.

Blood lead results reported at a concentration less than or equal to 1 µg/dL from the NHANES data for 2003 through 2010 supplied the known blood lead distributions used for the imputation method. Analytical methods employed for NHANES are highly precise resulting in very low detection limits ranging from 0.25-0.28 µg/dL. In fact, during the 2003 through 2010 survey years, only one non-detect value is reported in the NHANES blood lead data. Imputation from the NHANES data assumes that the distribution of BLLs less than 1 µg/dL for the Butte population is similar to the same distribution for the NHANES population. Given this assumption, for each two-year test period, the distributions of NHANES data less than or equal to 1 µg/dL were estimated using Oracle Crystal Ball. Then SAS Version 9.3 (SAS Institute Inc., Cary, NC, U.S.) was used to generate random samples from the appropriate distribution to impute a value for each Butte non-detect from the same two-year test period. In this manner, values that were represented more frequently in the NHANES data would be selected for replacement of Butte non-detect values more often.

In contrast to imputing Butte non-detects from the known NHANES distribution at or below 1 µg/dL, the final option extrapolates the Butte non-detect values from the population distribution of known Butte blood lead concentrations (i.e., the detected Butte data) using the EPA statistical software ProUCL's (Version 5.0, USEPA, Atlanta, GA) lognormal regression on order statistics (ROS) function for non-detect imputation . Values for non-detects were extrapolated/assigned from the Butte distribution of values from the same test year.

Employing each of the four non-detect treatment options, geometric mean BLLs were calculated for the Butte study data by two-year period. As shown in Figure 3, differences between each method are slight. The 2009-2010 test period had more non-detects than the other periods, and therefore, the treatment methods had larger effects on the geometric mean BLL. Although all options are scientifically justifiable and reasonably simple to execute, the extrapolation method was deemed most appropriate in that it utilizes known data from the Butte dataset. Therefore, the extrapolation method was selected for use in the study.

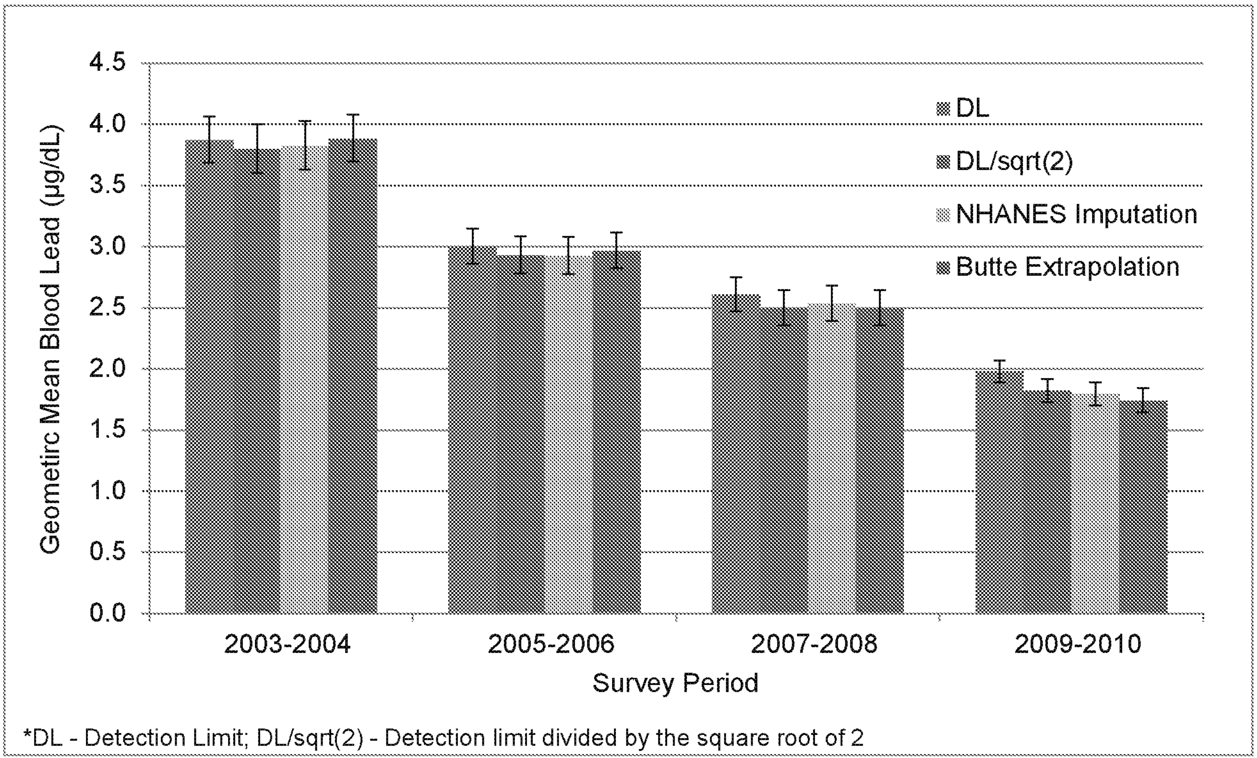


Figure 3: Comparison of Geometric Mean Blood Lead Estimates for Different Non-Detect Treatment Options

2.2.3 Statistical Treatment of Repeat Blood Lead Measurements for Individual Participants

The 2,796 records in the refined child dataset come from 1,697 unique children because study participants were often tested several times. Some children may have been tested annually during well child visits to the clinic, while others may have had repeat tests for other reasons. Multiple blood lead results from a single child cannot be considered statistically independent from each other because of common exposure conditions, as well as behavioral and physiological characteristics. Statistically it would be inaccurate to use multiple results from one child as though they are completely independent; however, if subsequent tests on individuals were removed from the dataset entirely, a significant amount of data would be lost. To keep these repeat measurements in the dataset, “mixed” models were used that could account for any interdependence in the repeat records. See sections 4.3 and 5.3 for additional details on the models.

2.2.4 Butte Blood Lead Summary Statistics

Summary statistics for the refined Butte dataset are presented in Table 1.These data represent screening BLLs, not confirmed venous results. These data also include repeat measurements.

Table 1: Butte Blood Lead Summary Statistics

Year	N	GM (µg/dL)	GSD (µg/dL)	95th percentile (µg/dL)	% ≥ 5.0 µg/dL	% ≥ 10.0 µg/dL
2003	351	3.49	2.01	9.10	33.6	3.4
2004	319	4.36	1.76	9.51	44.8	4.4
2005	312	3.35	1.83	8.60	24.7	2.6
2006	326	2.63	1.93	7.03	16.0	1.8
2007	342	2.44	2.16	7.90	16.1	2.0
2008	324	2.55	2.15	9.15	20.1	4.0
2009	361	2.01	2.10	6.80	10.8	1.4
2010	461	1.55	2.42	6.60	9.5	1.5

N – Sample Size; GM – Geometric Mean; GSD – Geometric Standard Deviation

As shown in Table 1, blood lead levels in Butte children have dropped dramatically since 2003. Geometric mean BLLs for 2010 (1.55 µg/dL) were less than half of the levels for 2003 (3.49 µg/dL). The percent of BLLs above 10.0 µg/dL declined by a similar magnitude, decreasing from 3.4 percent to 1.5 percent. The percent of BLLs above 5 µg/dL declined by an even greater margin, decreasing from 33.6 percent in 2003 to 9.5 percent in 2010.

3 General Factors Influencing Blood Lead Levels

Lead exposures of children are a concern in all U.S. communities. Many sources and risk factors are associated with higher blood lead levels in children. Sources found in most communities include lead in house paint (from before 1978), lead in plumbing (pipes, brass fittings and solder) and lead in various consumer products such as toys, lead glazed ceramic dishware, and old mini-blinds, as well as lead associated with hobbies such as making fishing sinkers or bullets, and stained glass. Elevated lead blood lead levels have been found at homes where batteries are recycled or where parents track home lead on clothes contaminated at work. Higher blood lead levels are also associated with poverty and other demographic and socioeconomic factors. In Butte, lead in soil and dust that originates from wastes generated by historical mining operations is also a concern and is the primary reason for the Superfund activities.

BLLs have declined precipitously in all U.S. populations since the 1970s with implementation of the ban on lead additives in gasoline and paint, along with control of lead in plumbing, canned foods, and other sources. Nevertheless, a variety of factors continue to be associated with differences in BLLs across the nation. These include demographic factors such as gender, age, and race/ethnicity, as well as a variety of socioeconomic factors such as income level and maternal education. To the extent that such information was available for both Butte and the reference dataset (NHANES), these general factors have been considered in the models developed to address the principal study question, in order to differentiate them from factors unique to Butte.

3.1 Sample Year, Season, Age and Gender

Three primary factors considered in model development are the year in which the sample was collected, the season in which the sample was collected, and the age of the subject tested. BLLs may also vary by gender, but this is not currently a significant factor for all age cohorts based on national data.

As noted above, BLLs have declined over the past few decades and continue to decline, albeit at a slower rate in recent years. In addition, BLLs in young children have long been known to be highest in summer and early autumn (Hayes et al. 1994). This pattern has been assumed to be associated with greater exposure to soil containing lead, due to more time spent outside and to more soil tracked and blown into the house during the summer months. A recent study of BLLs in Detroit area children has confirmed that this pattern still occurs; with late summer BLLs averaging between 11 percent and 14 percent higher than BLLs measured in January (Zahran et al. 2013). A preliminary analysis of the Butte dataset (not presented) suggested that a similar trend was present among Butte children.

It has also been consistently observed in the U.S. that on average young children between the ages of 1 and 3 years have the highest BLLs among children (Jones et al. 2009; CDC 2013b). Figure 4 shows the continued decline in BLLs in successive birth cohorts, as well as the decline in BLLs as each birth cohort gets older. Blood lead data collection focuses on young children because their BLLs are higher than other age groups and because young children are more sensitive to the impacts of lead than are older children and adults. Preliminary analyses of all available Butte blood lead records[8] confirm that BLLs have been trending down over the period from late 2002 to late 2011, and that BLLs are higher in 1 to 5 year old children compared with older children and adults living in Butte (Figure 5).

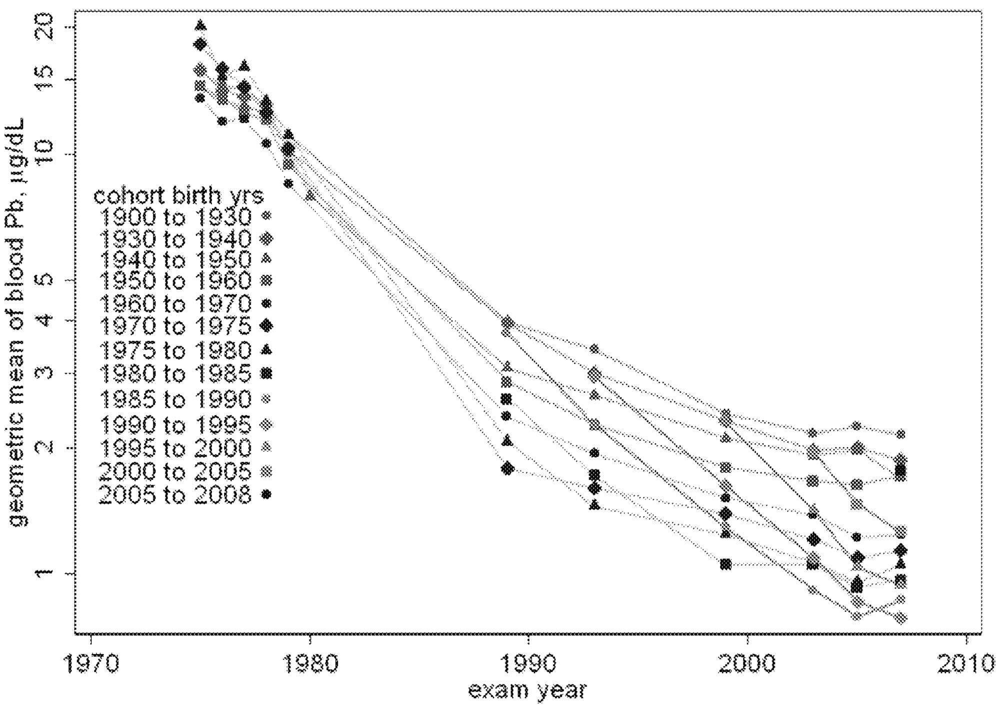


Figure 4: Decline in Blood Lead in Different NHANES Birth Cohorts (USEPA 2013a)

[8] Excluding LeadCare II records

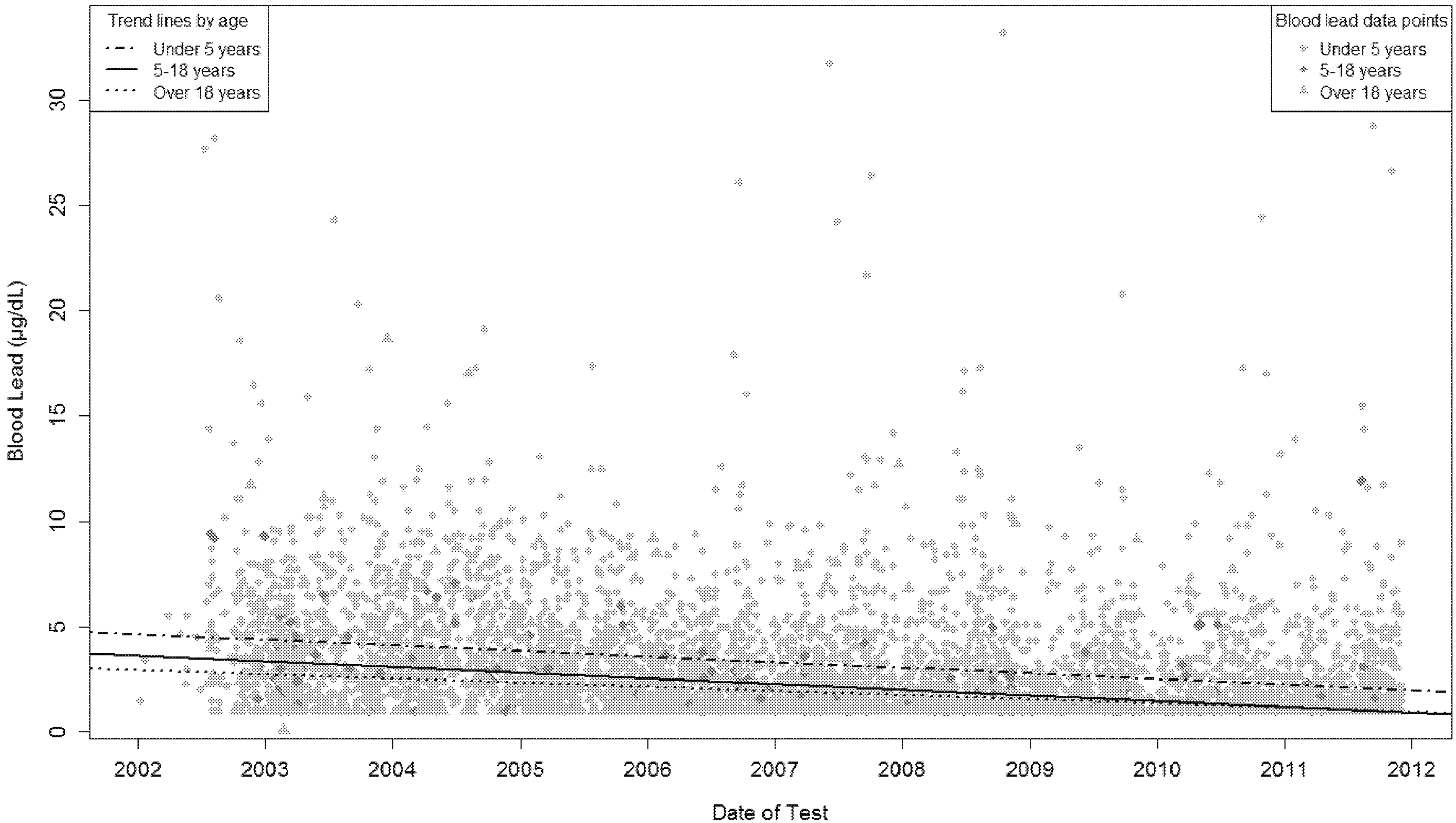
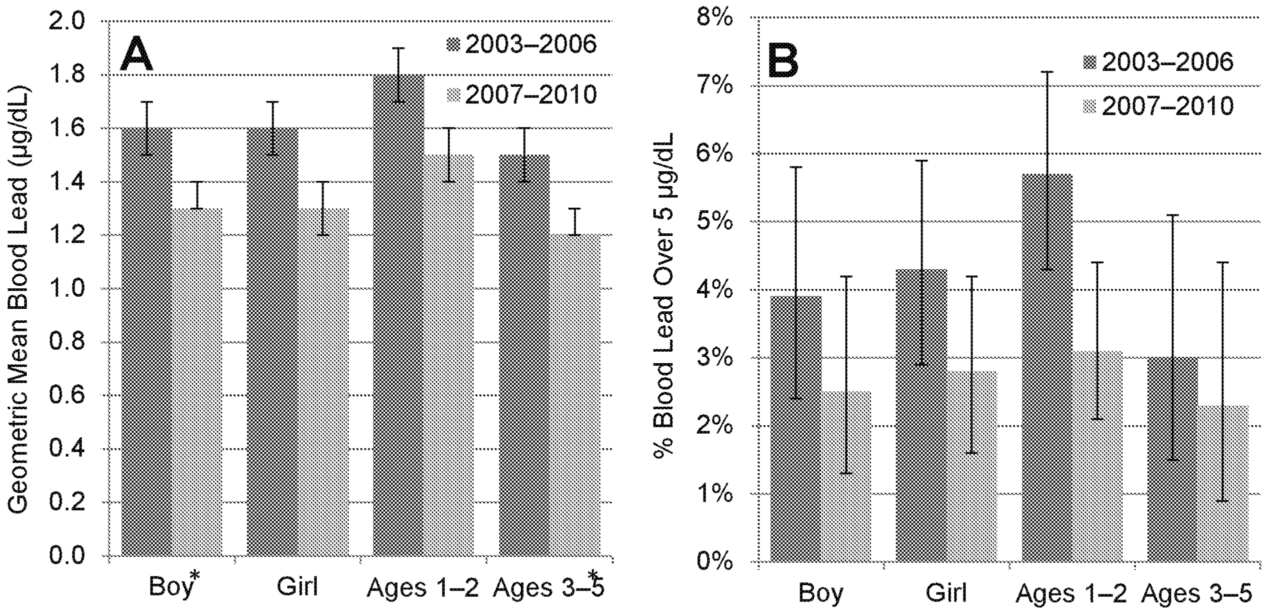


Figure 5: Butte Blood Lead over Time by Age Group for Individuals Aged 1 Year or Older (excluding LeadCare II Results)

BLLs also vary by age within the 1 to 5 year old cohort. Even as BLLs have declined over time, the ages with peak average BLLs have consistently remained from 1 year up to 3 years (Jones et al. 2009; CDC 2013b).In contrast, there have not been consistent gender-related differences in BLLs in young children in the U.S during the past ten years. Figure 6 illustrates these factors for the NHANES dataset for two time periods (2003-2006 and 2007-2010).



*The lower confidence limit equal to the mean is due to rounding

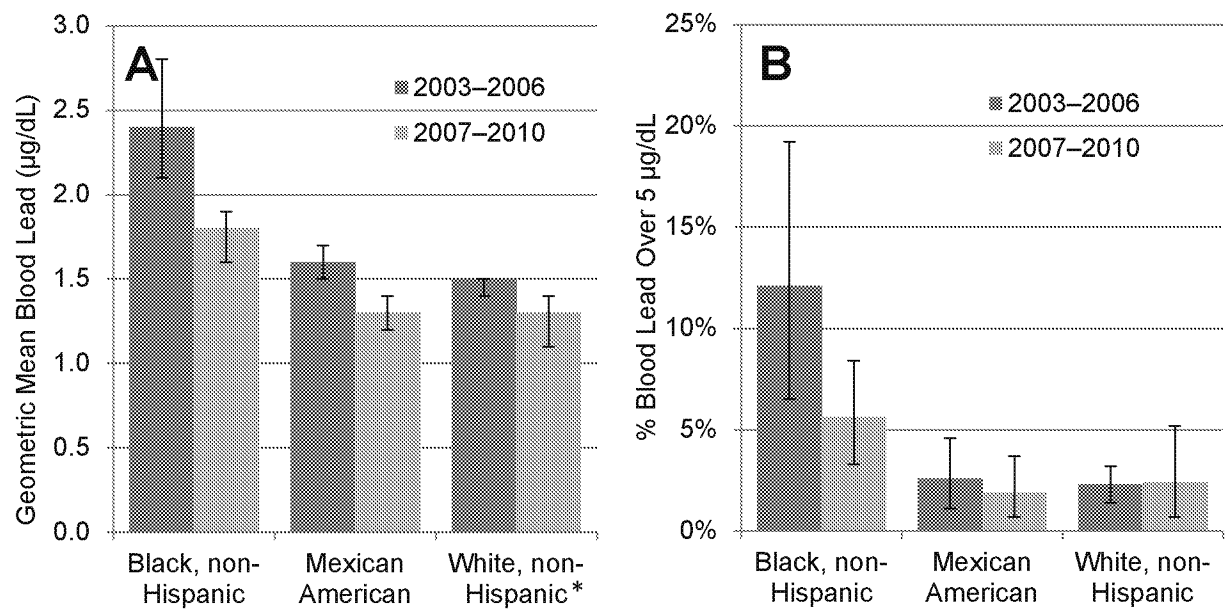
Figure 6: Geometric Mean Blood Lead (A) and Percent Blood Lead over 5 µg/dL (B) by Gender and Age Group from U.S. Children Ages 1 to 5 Years with 95% Confidence Intervals (CDC 2013b)

3.2 Demographic and Socioeconomic Factors

Demographic and socioeconomic factors such as race/ethnicity, income level, educational attainment of mother, and housing status have been correlated with BLLs in children and are important to consider in comparing BLLs for different groups when possible (Sargent et al. 1995, CDC 2000, Gee and Payne-Sturges 2004, CDC 2013b, Jones et al. 2009).

The relative importance of these factors is likely to vary over time. For example, while the difference in BLLs between non-Hispanic black children vs. non-Hispanic white children is still significant, the magnitude of the difference has decreased substantially over time (CDC 2013b). Jones et al. (2009) and CDC (2013b) provide summaries of trends in the primary demographic and socioeconomic factors for U.S. children from 1988 through 2010, as summarized below.

Race/Ethnicity – Race continues to be a significant risk factor for elevated BLLs with the highest levels on average reported for non-Hispanic black children. Figure 7 illustrates race and ethnicity differences in geometric mean BLLs and percentage of BLLs greater than 5 µg/dL from a national dataset for two time periods during the past decade. As shown in Figure 7, average BLLs are higher in non-Hispanic black children, and the percent of these children with BLLs greater than 5 µg/dL is more than twice as high as the percent of non-Hispanic white and Mexican children with elevated BLLs.



*The upper confidence limit equal to the mean is due to rounding

Figure 7: Geometric Mean Blood Lead (A) and Percent Blood Lead over 5 µg/dL (B) by Race/Ethnicity from U.S. Children Ages 1 to 5 Years with 95% Confidence Intervals (CDC 2013b)

Poverty status – Children living in poverty have higher BLLs compared with children in wealthier households. Two measures are used in national studies to assess poverty status: the poverty to income ratio and Medicaid enrollment. The poverty to income ratio (PIR) is the total family income divided by the federal poverty level specific to family size, year, and state of residence. Figure 8 compares geometric mean BLLs and percentage of BLLs greater than 5 µg/dL for children from low income households (defined as a PIR of less than 1.3) with those from higher income households. This figure also compares BLLs for children enrolled in Medicaid with those not enrolled. Both of these measures of poverty status are associated with higher mean BLLs and substantially higher percentages of children with BLLs greater than 5 µg/dL

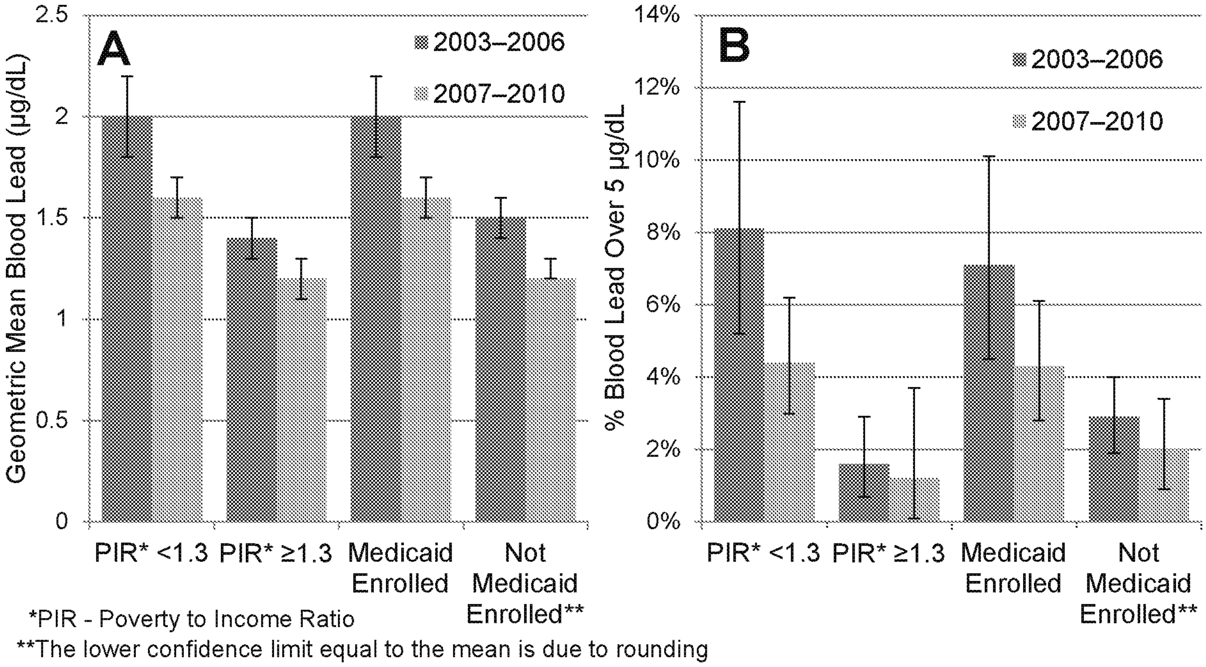


Figure 8: Geometric Mean Blood Lead (A) and Percent Blood Lead over 5 µg/dL (B) by PIR and Medicaid Status from U.S. Children Ages 1 to 5 Years with 95% Confidence Intervals (CDC 2013b)

House age[9] – Older housing in the U.S. is associated with higher BLLs for a variety of reasons, including the historical use of exterior and interior paint with added lead and higher frequency of lead plumbing lines and fixtures in older homes. Lead paint is primarily a concern when the paint condition deteriorates, so poverty status and living in rental housing are related factors that may contribute to greater exposure to lead paint in older housing.

[9] Throughout the study, the term “house” refers to any residential dwelling, including single family homes as well as multifamily housing complexes and “house age” refers to the range of years within which the house was built.

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Lead content of paint was reduced over several decades prior to its ban in the U.S. in 1978. Figure 9 shows the influence of house age on average and elevated BLLs for several categories, including when house age information was missing. As can be seen from this figure, the percent of children with elevated BLLs is markedly higher for those living in U.S. housing built prior to 1950.

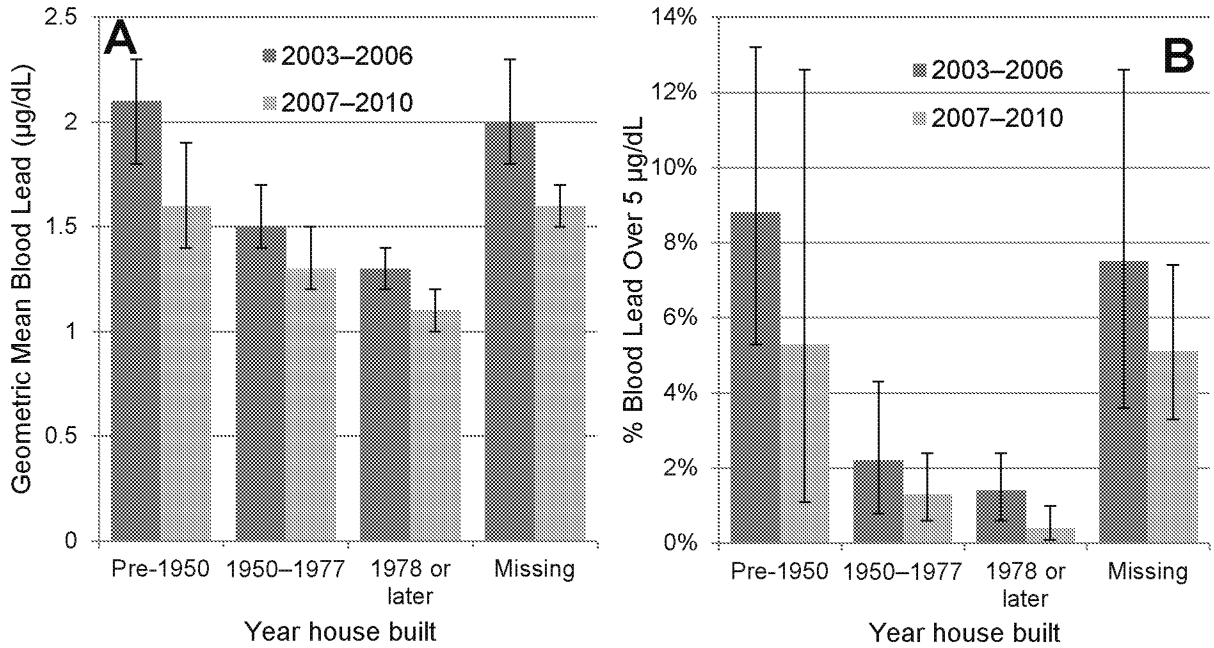


Figure 9: Geometric Mean Blood Lead (A) and Percent Blood Lead over 5 µg/dL (B) by House Age from U.S. Children Ages 1 to 5 Years with 95% Confidence Intervals (CDC 2013b)

4 Butte vs. NHANES Comparison

As described in section 1, two lines of evidence are evaluated in this study to address the principal study question. The first line of evidence evaluated in this study addresses whether or not the distributions of BLLs in the Butte community and in a reference population are similar over the same period evaluated. The NHANES dataset was proposed as the reference population for use in this study as detailed in a technical memorandum (ENVIRON 2013b) submitted to EPA on August 20, 2013. NHANES was proposed based on the availability of a large blood lead dataset for the sample years and age ranges included in the Butte dataset, as well as the ability to correct for several factors that are strongly associated with BLLs. EPA, in consultation with MDEQ, approved selection of NHANES for this study on September 3, 2013. The approved technical memorandum is included as Appendix D to this report.

The remainder of this section describes factors considered in development of a statistical model to compare the Butte and NHANES datasets and details the model development process. Model results are also presented along with a summary of overall conclusions from this analysis.

4.1 Key Factors that Influence BLLs that were Considered in Development of the Butte vs. NHANES BLL Comparison

The Butte vs. NHANES comparison seeks to understand how the BLLs of the children in Butte compare to a reference dataset from the national population across the same time periods and test ages. The NHANES program assesses the health and nutrition of the U.S. population across all age groups. The surveys enroll approximately 10,000 participants across the nation for every two-year survey period, collecting extensive health and dietary information, venous blood lead results, and demographic information.[10]

The NHANES data are reported for two-year time periods. Blood lead data in NHANES for 2003-2004, 2005-2006, 2007-2008, and 2009-2010 are available for comparison to Butte blood lead data for the same time periods. From these years, the NHANES data was limited to 2,937 records from children matching the study age range (12-60 months) who had a blood lead record. The characteristics of the NHANES child blood lead data are summarized in Table 2.

[10] More information about this program may be found at: http://www.cdc.gov/nchs/nhanes.htm

Table 2: Characteristics of NHANES Child Blood Lead Data

2-Year Survey Period	Blood Lead Sample Size	Age Range (months)	Number of Non-detects	Collection Method
2003-2004	753	12-60	0	Venous
2005-2006	806	12-60	0	Venous
2007-2008	676	12-60	0	Venous
2009-2010	702	12-60	1	Venous

When comparing the Butte data to the NHANES data, the goal was to determine if factors that are unique to Butte explain differences between BLLs of children in this area compared to children outside of Butte. To ensure meaningful comparisons, it is important to consider how Butte and the other population compare in terms of common factors that influence BLLs, but are not unique to Butte. When population differences are apparent, investigators commonly use weighting procedures to better match the reference population to the study population. Adjusting for population differences in this way is not unique to this study. In fact, the CDC applies weights to the NHANES data to make it representative of the U.S. population (CDC 2013a).

Key factors influencing BLLs were described in section 3 and include gender, age, and test year, as well as demographic factors such as racial composition, poverty level, and house age. To the extent that information about these factors is available for blood lead records in the Butte and NHANES datasets, such information can be used in model development to weight the NHANES data to be comparable (in terms of demographics and other non-blood lead factors) to the Butte data. Gender, child age and house age are available for individual records in both datasets. Specific test dates are available for Butte, but for NHANES the test date falls within a two-year time period.[11] Poverty and race data are not available for individual records in the Butte dataset as they are for NHANES. However, as described in the following two sections, there is sufficient information about the Butte community and test population to support consideration of these factors in the population comparison. Once differences between the Butte and NHANES data were considered with respect to study variables, weights were calculated for each variable to determine the variables that were most different between the two populations (see section 4.3.2). Final weights were then applied to the NHANES data in statistical model analyses that compared Butte to the NHANES data using standard weighting procedures in SAS Version 9.3 (SAS Institute Inc., Cary, NC), the statistical software used in this study (see section 4.3.3 and Appendix E).

A summary of specific differences between the two datasets is provided below.

4.1.1 Poverty Data Differences

Poverty to income ratios, or PIR, are available for most records in the NHANES dataset, but poverty level information for the Butte data was not requested at the time of sample collection.

[11] NHANES records include a variable for the six month period within each two-year period that the data were collected, allowing for comparison between samples taken November 1 – April 30 (winter/spring) and samples taken May 1 – October 31 (summer/fall).

For children in the NHANES dataset who were missing poverty information, PIR values were imputed from the other NHANES records with known PIRs. In the Butte sample population, the majority of the records were collected through the WIC program from residents who qualified for the assistance by being at or below 175 percent of the federal poverty level, the WIC eligibility threshold. Other individuals tested via Butte's WIC program may have been referred by a private physician or the RMAP. In these cases, the individual's WIC status may or may not have been known. However, based on communications with BSB and WIC staff, the proportion of individuals tested who were not known to qualify for WIC is very small. Therefore, the assumption was made that the vast majority of the Butte blood lead records (90-95 percent) correspond to children from families with household incomes at or below 175 percent of the federal poverty level. This WIC eligibility threshold is equivalent to a PIR of 1.75 in the NHANES dataset. The relationship between WIC eligibility and PIR provides a basis for comparing the two datasets in terms of poverty level. As described further in section 4.3.2.6, a sensitivity analysis was used to test the relative impact of different poverty assumptions for the Butte study population prior applying the weights in the statistical model.

4.1.2 Differences in Racial Composition

Unlike the NHANES dataset, record-specific racial data for the Butte dataset is not available. As summarized in Table 3 below, estimate data from the U.S. Counties Census are available for Butte-Silver Bow County and may be used to infer the racial composition of the Butte dataset. More specific data on racial composition by census tract are not available except with the 2000 and 2010 full census data. A review of the full census data by tract did not suggest that the racial composition was substantially different from the county-wide estimates.

Table 3: Racial Composition for Butte-Silver Bow County

Race/Ethnicity	2003-06	2007-10
Non-Hispanic white	92.4%	91.9%
Non-Hispanic black	0.2%	0.3%
Hispanic or Latino origin	3.1%	3.5%
Other race- including multiracial	4.2%	4.4%
Source: U.S. Counties Census estimates for 2003-2010		

The racial composition of the NHANES blood lead dataset is summarized in Table 4 and shows a much more diverse racial composition in contrast to Butte.

Table 4: Race/ethnicity for NHANES Blood Lead Data from 2003-2010

Race/Ethnicity	2003-06	2007-10
Non-Hispanic white	28%	28%
Non-Hispanic black	28%	18%
Mexican American	33%	26%
Other Hispanic	6%	10%
Other race - including multiracial	6%	6%

For the purposes of this study, it was assumed that the racial composition of Butte-Silver Bow County as a whole is the same as the racial composition of the Butte blood lead data population. Based on this assumption, the NHANES population could be weighted to make it more racially comparable to the Butte population.

4.2 Other Differences Between the Butte and NHANES Blood Lead Data

In addition to factors that may influence BLLs in the general population, other differences between how blood lead data are collected and analyzed in the Butte and NHANES datasets are important. For instance, the method of recruiting participants for each dataset differs. The majority of participants in the Butte dataset represent individuals enrolled in the WIC program. Households with income at or below current WIC income guidelines are offered WIC services free of charge, including annual testing for blood lead. A smaller proportion of the overall Butte dataset is represented by individuals referred for blood lead testing through a primary care physician or the RMAP, some of whom may also qualify for enrollment in WIC. Poverty rates for WIC eligible individuals are likely to be higher than the general Butte population. Individuals living at higher poverty levels are more likely to live in older housing that is associated with increased sources of potential lead exposure.

The NHANES program recruits participants using a complex, multistage probability sampling design that intentionally oversamples subpopulations of interest within a given survey period. As a result, prior to using NHANES data for analyses of national BLL trends, the CDC applies weights to the raw NHANES data to be representative of the U.S. population.

In addition to recruitment differences, the blood lead sample collection and analytical methods for Butte and NHANES also differ. In Butte, blood lead data were collected onto filter paper from capillary samples typically obtained from a child's finger. Sample data of this type is considered appropriate for blood lead screening, but must be confirmed by venous sampling when elevations are suspected. While venous confirmation was conducted in Butte when screening results exceed 9.9 µg/dL, venous data were excluded from the Butte dataset used in this study as described in section 2.1. In contrast, the NHANES blood lead data are all based on venous blood draws. A key concern with the use of finger stick sample collection is the potential for external contamination of the blood sample from lead on the skin which is very difficult to remove completely (ACCLPP 2012). Such external contamination could bias Butte sample results high compared to NHANES sample results. However, correlation coefficients between capillary and venous methods have been reported to range from 0.96-0.98 in paired testing (Schlenker et al. 1994) and Butte WIC sample collection methods include preparation of the skin location using laboratory-provided wipes that are designed to reduce the potential for external lead contamination. Additionally, the laboratory used for the Butte blood lead data reports:

> "The correlation between paired, simultaneously drawn extraction method filter paper and venous samples is >.970. Additionally, undetected-elevated and, falsely-elevated rates may be considered clinically insignificant. These findings are documented by three published, peer-reviewed studies involving 363 paired, simultaneously drawn extraction method filter paper and venous sample comparisons." (Yee et al. 1995; Srivuthana et al. 1996; and Yee 1997)

In addition to sample differences, there are also analytical differences between the Butte and NHANES data. The analytical method sensitivity of Butte blood lead measurements is lower than that of the NHANES data as reflected in higher detection limits for Butte than for NHANES. As discussed in section 2.2.2, unknown blood lead concentrations below the Butte detection limit (1 µg/dL) were extrapolated from the known distribution of blood lead concentrations in the Butte dataset to improve comparability of the Butte and NHANES datasets given these analytical differences.

4.3 Butte vs. NHANES Model Development

The Butte vs. NHANES comparison required a statistical model that allowed for the comparison of BLLs (the dependent variable) between the Butte and NHANES sample populations of children 12-60 months of age while accounting for other independent variables that can influence blood lead, as described in section 3.

The software used to perform these statistical analyses was SAS Version 9.3 (SAS Institute, Inc., Cary, NC). Because many children in Butte have repeated BLL measurements, linear mixed models were used to account for the correlated nature of the data. The "MIXED" procedure in SAS was used for all of the models because it is able to handle these repeated/correlated data as well as data with a different number of measurements per subject. When using the SAS "MIXED" procedure, a covariance structure or specification about how the measurements are related over time was chosen. An autoregressive covariance structure was used in the models, meaning that measurements farther apart in time are assumed to be less correlated than observations closer in time. The SAS "MIXED" procedure provides f-tests from the "Type 3 Tests of Fixed Effects," which were used to determine the overall significance of variables, as well as partial t-tests from the "Solution for Fixed Effects," which were used to determine the significance of the different levels/categories of each variable compared to a reference. Additionally, a "Least Squares Means" (LSMEANS) statement was used to calculate geometric means and 95 percent confidence intervals for all categorical variables.

The first step of the model development was generating the univariate statistics. Univariate analysis examined each independent variable individually to determine whether it influenced the dependent variable, BLL. Based on the results from the univariate analysis, a fully adjusted multivariable model was built. An *a priori* decision was made that the fully adjusted model would include all variables that were significant ($p<0.05$) before weighting in the univariate analysis. In a fully adjusted model, the effects of each independent variable on BLLs are examined after adjusting for all of the other variables included in the model.

Before running the fully adjusted model, the Butte vs. NHANES comparison required a weighting procedure to ensure that the NHANES population demographics more closely matched the Butte sample population's demographics (section 4.3.2). This procedure necessitated determining which of the available variables should be used to weight the NHANES records. Variables for which NHANES values vary most from corresponding Butte values were selected for weighting, and the final weights were applied to the NHANES data using standard SAS weighting procedures.

Interaction terms of interest were then examined in the fully adjusted model. The final model was then stratified based on data source, Butte or NHANES. Once stratified, adjusted geometric mean BLLs for each independent variable included in the model were presented for a side-by-side comparison of Butte and NHANES.

The process and information used to develop the final stratified statistical model for the Butte vs. NHANES comparison is presented below.

4.3.1 Identification of Significant Variables for Inclusion in the Model

The first step in building the Butte vs. NHANES comparison model required identification of independent variables that should be included in the model. Univariate statistical analyses were performed to determine the significance of each independent variable with regard to its influence on blood lead. Table 5 summarizes the details for each variable examined for the Butte dataset. Table 6 summarizes the details for each variable examined from the NHANES dataset. For each variable in the univariate analysis, models produced estimates and p values from t-tests, as well as geometric mean BLLs with a 95 percent confidence interval around the mean.

Table 5: Results from Univariate Analysis for Butte Data in Butte vs. NHANES Comparison

Variable	N	GM/Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p value
Child test age (estimate)	2796	0.96	0.94	0.99	0.0020*
Child gender					
Male	1441	2.68	2.55	2.81	Reference
Female	1355	2.31	2.20	2.43	<0.0001*
Year house built					
Missing	991	2.40	2.28	2.53	<0.0001*
Post 1977	111	1.67	1.44	1.95	<0.0001*
1960 to 1977	153	2.21	1.94	2.52	0.0007*
1950 to 1959	158	2.23	1.95	2.56	0.0018*
1940 to 1949	244	2.37	2.13	2.63	0.0035*
Pre 1940	1139	2.81	2.67	2.95	Reference
Test year					
2003-2004	670	3.79	3.57	4.02	<0.0001*
2005-2006	638	2.90	2.73	3.08	<0.0001*
2007-2008	666	2.43	2.30	2.58	<0.0001*
2009-2010	822	1.69	1.60	1.78	Reference
Test season					
Winter/Spring	1414	2.29	2.19	2.39	<0.0001*
Summer/Fall	1382	2.71	2.59	2.83	Reference

*Statistically significant ($p \leq 0.05$)
N – Sample size; GM – Geometric mean; GSD – Geometric standard deviation; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit-less.

Table 6: Results from the Univariate Analysis for NHANES Data in Butte vs. NHANES Comparison

Variable	N	GM/Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p value
Child test age (estimate)	2937	0.94	0.92	0.96	<0.0001*
Child gender					
Male	1510	1.68	1.62	1.73	Reference
Female	1427	1.7	1.64	1.76	0.58
Child race/ethnicity					
Non-Hispanic White	882	1.52	1.46	1.59	Reference
Hispanic	917	1.49	1.44	1.55	0.48
Non-Hispanic Black	715	2.34	2.24	2.45	<0.0001*
Other Race	176	1.68	1.53	1.84	0.062
Year house built					
Missing	1023	1.96	1.88	2.03	<0.0001*
Post 1977	868	1.33	1.27	1.39	<0.0001*
1960 to 1977	397	1.51	1.42	1.61	<0.0001*
1950 to 1959	244	1.68	1.55	1.81	<0.0001*
1940 to 1949	113	1.73	1.55	1.95	<0.0001*
Pre1940	292	2.38	2.21	2.55	Reference
Test year					
2003-2004	753	2.14	2.05	2.24	<0.0001*
2005-2006	806	1.69	1.62	1.76	<0.0001*
2007-2008	676	1.69	1.61	1.77	<0.0001*
2009-2010	702	1.31	1.25	1.37	Reference
Test season					
Winter/Spring	1389	1.5	1.45	1.55	<0.0001
Summer/Fall	1548	1.88	1.82	1.94	Reference

*Statistically significant ($p \leq 0.05$)

N – Sample size; GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit-less.

The univariate statistics from the Butte dataset are significant for all variables: child test age, child gender, year house built, test year, and test season (Table 5). The NHANES univariate results (Table 6) show that the majority of the variables are significant. For race, the black population has significantly higher BLLs than the reference (non-Hispanic whites). The other races do not differ from the reference significantly. Child gender differences are not significant in the NHANES dataset (p=0.58). The F-tests from the univariate analyses were performed to determine which variables were significant for inclusion in the fully adjusted model.[12] The p values from the F-test results for the Butte univariate models, the NHANES univariate models, and the univariate models with Butte and NHANES data combined are presented in Table 7. Because child race/ethnicity data was not available for individual records in Butte, it was not included as a variable beyond the univariate analysis, though it was retained for consideration in the NHANES weighting.[13] All other variables were significant in the Butte and/or NHANES datasets and significant when the datasets were combined. Therefore, they were all included in the fully adjusted model.

Table 7: Results from F-test for all Variables in Univariate Analysis for Butte vs. NHANES

Variable	p Value – Butte Only	p Value – NHANES only	p Value – Butte and NHANES Combined
Child test age	<0.002*	<0.0001*	<0.0001*
Child gender	<0.0001*	0.58	0.012*
BLL source (NHANES or Butte)	-	-	<0.0001*
Year house built	<0.0001*	<0.0001*	<0.0001*
Test year	<0.0001*	<0.0001*	<0.0001*
Test season	<0.0001*	<0.0001*	<0.0001*

*Statistically significant ($p \leq 0.05$); BLL – Blood lead level; NHANES results are not weighted

4.3.2 Weighting the NHANES Data

As stated in section 3, there are many factors that can affect BLLs. When comparing the Butte data to the NHANES national data, the goal was to determine if factors that are unique to Butte are causing a difference in the BLLs of the children in this area. In order to see this, it was important to decrease the influence of any other differences that might be present between the Butte population and the NHANES population. For example, the Butte dataset contains children who have higher poverty overall than the NHANES dataset. Poverty is known to be related to higher BLLs. If these two datasets were compared without adjusting NHANES for this variable, it would be difficult to explain whether BLL differences between Butte and NHANES were related to poverty level differences or other factors.

Recruitment for NHANES includes diverse subpopulations and geographical areas of the U.S. and varies by survey period, oversampling certain populations of interest in different years. The CDC provides "weights" to apply to the NHANES dataset to make it representative of the nation. Similarly, for the purposes of this study, the NHANES population needs to be adjusted using weights to make it representative of the Butte population.

Once final weights were calculated for selected variables (i.e., those most different between the two populations), the weights were then applied in the statistical model analyses on the NHANES data using standard weighting procedures in SAS.

[12] For variables with only two categories, such as gender, the results of the F test are the same as the p values presented in the univariate results tables.
[13] Outside of the model, race was considered in generating the weights for NHANES, section 4.3.

The demographic variables considered for weighting were child test age, child gender, test season in which the blood test was done, age of house, child ethnicity, and a YES/NO indication of poverty. Data for each of the variables were available for each of the NHANES records.[14] For the Butte records, data were available for all but two variables: poverty and race. Estimation of Butte data for these variables was necessary prior to evaluating all variable weights for possible inclusion the Butte vs. NHANES comparison model. Weights evaluated for each of these variables are described in the following sections along with assumptions and information used to estimate Butte poverty and race data for the weighting evaluations summarized below and in section 4.1.

4.3.2.1 Child Test Age Data Weights

Weights were determined for the NHANES data based on child test age distribution from the Butte population. As shown in Table 8, the weights are not very different from one. Given the similarity of data distributions for this variable, weighting NHANES for child test age was determined to be unnecessary.

Table 8: Weights for NHANES Based on Butte Age Distribution

Child Test Age (months)	Year group	Weight*
12-35	2003-2004	0.92
36-60		0.85
12-35	2005-2006	0.78
36-60		0.80
12-35	2007-2008	1.0
36-60		0.91
12-35	2009-2010	1.2
36-60		1.1

*Weight - ratio of Butte to NHANES counts

4.3.2.2 Child Gender Data Weights

Weights were determined for the NHANES dataset based on the child gender distribution from the Butte dataset (Table 9). The weights are not very different from one for any of the groups given the similar distributions of gender data for both datasets. Therefore, weighting based on this variable was determined to be unnecessary.

[14] A subset of NHANES records (n=163) were missing poverty information. For these records, poverty was imputed using a uniform distribution to avoid excluding NHANES children missing poverty information.

Table 9: Weights for NHANES Based on Butte Gender Distribution

Gender	Year group	Weight*
Female	2003-2004	0.94
Male		0.84
Female	2005-2006	0.69
Male		0.89
Female	2007-2008	0.96
Male		1.0
Female	2009-2010	1.3
Male		1.1

*Weight - ratio of Butte to NHANES counts

4.3.2.3 Test Season Data for Weights

Weights were determined for NHANES based on the test season distribution from the Butte dataset (Table 10). The weights are not very different from one. Therefore, weighting based on this variable was determined to be unnecessary.

Table 10: Weights for NHANES Based on Butte Distribution for Test Season

Season	Year group	Weight*
Winter/Spring	2003-2004	1.1
Summer/Fall		0.69
Winter/Spring	2005-2006	0.86
Summer/Fall		0.73
Winter/Spring	2007-2008	1.0
Summer/Fall		0.96
Winter/Spring	2009-2010	1.1
Summer/Fall		1.2

*Weight - ratio of Butte to NHANES counts

4.3.2.4 House Age Data Weights

House age data collected for Butte and NHANES were categorized as shown in Table 11 based on the year the house was built. Rather than excluding children missing year house built information, a separate missing category was created.

Table 11: Percent Year House Built Distribution for Blood Lead Records from Butte

Year house built category	2003-06	2007-10
Missing	35.2	35.6
Post 1977	3.4	4.4
1960-1977	6.0	5.0
1950-1959	6.4	5.0
1940-1949	7.8	9.5
Pre1940	41.1	40.5

As shown in Table 12, the resulting weights for NHANES based on this distribution of year house built in Butte are very different from one, suggesting the importance of adjusting the NHANES data for year house built in the statistical model.

Table 12: Weights for NHANES Based on Butte Year House Built Distribution

Year house built	Year group	Weight*
Missing	2003-2004	0.72
Post 1977		0.15
1960-1977		0.34
1950-1959		0.54
1940-1949		2.0
Pre 1940		3.9
Missing	2005-2006	0.89
Post 1977		0.076
1960-1977		0.38
1950-1959		0.79
1940-1949		1.3
Pre 1940		4.0
Missing	2007-2008	1.2
Post 1977		0.11
1960-1977		0.34
1950-1959		0.61
1940-1949		3.0
Pre 1940		3.5
Missing	2009-2010	1.1
Post 1977		0.21
1960-1977		0.50
1950-1959		0.64
1940-1949		2.6
Pre 1940		4.2

*Weight - ratio of Butte to NHANES counts

4.3.2.5 Race Data Weights

Child race in the Butte records was inferred from the census data as described in section 4.1.2. Specifically, it was assumed that the Butte study population's racial composition was identical to that of BSB County as a whole. County level data (U.S. Census Bureau 2010) were then used to calculate the relative percentages of each race category for two four-year periods, 2003-2006 and 2007- 2010 (Table 13). The Butte race distribution based on these percentages was then used with the NHANES race distribution to calculate race weights. As shown in Table 13, the race weights are very different from one. The smallest weight is 0.0057 for the black, non-Hispanic group from 2005-2006, while the largest is 3.4 for the white, non-Hispanic group from 2009-2010. As reflected by these weights, the racial distribution in NHANES is very different from Butte for every test year group supporting adjustment of the NHANES data for this variable in the statistical model.

Table 13: Weights for NHANES Based on Butte Racial Distribution

Race	Year group	Weight*
Other/multiracial	2003-2004	0.67
Hispanic		0.080
Black, non-Hispanic		0.0057
White, non-Hispanic		2.9
Other/multiracial	2005-2006	0.56
Hispanic		0.061
Black, non-Hispanic		0.0065
White, non-Hispanic		2.6
Other/multiracial	2007-2008	0.82
Hispanic		0.082
Black, non-Hispanic		0.013
White, non-Hispanic		2.8
Other/multiracial	2009-2010	0.71
Hispanic		0.098
Black, non-Hispanic		0.019
White, non-Hispanic		3.4

Source: U.S. Counties Census estimates for 2003-2010
*Weight - ratio of Butte to NHANES counts

4.3.2.6 Poverty Data Weights

As described in section 4.1.1, poverty designations for children in the Butte dataset were inferred based on an assumption that the majority of the children tested (90-95 percent) were WIC eligible and that WIC eligibility status was equivalent to a PIR value in NHANES of 1.75. Prior to applying weights for poverty, a sensitivity analysis was performed to evaluate the relative significance of assuming 90 or 95 percent of the Butte study population were WIC eligible. As shown in Figure 10, the weighting assumptions do not significantly change the NHANES geometric mean BLLs by two-year period. Therefore, for the final weighting, the 95 percent assumption was used.

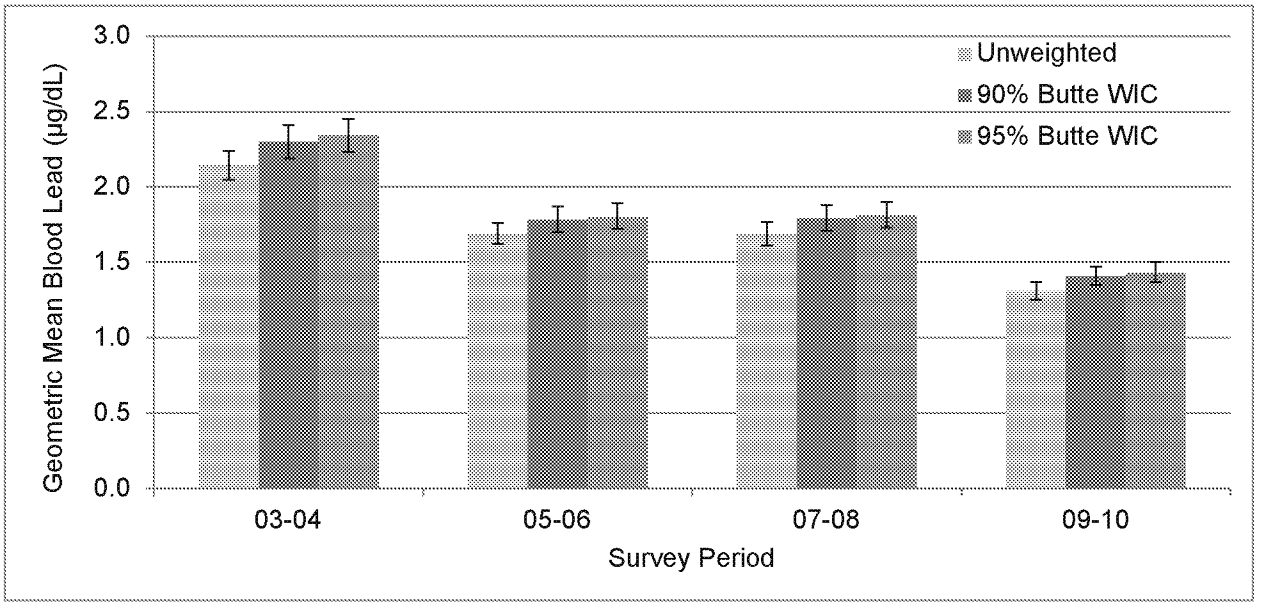


Figure 10: NHANES Geometric Mean Blood Lead and 95% Confidence Intervals for NHANES Weighting Scenarios Where 90% or 95% of Butte Sample Qualifies for WIC (PIR ≤ 1.75)

Table 14 summarizes poverty weights calculated based on an assumption that 95 percent of the Butte study population was WIC eligible. The lowest weight (0.11) corresponds to the lesser poverty category (PIR >1.75) for the 2005-2006 test period. The highest weight (1.8) is calculated for the greater poverty category (PIR ≤1.75) for the 2009-2010 test period. Evaluation of these weights supports adjustment of the NHANES data in the statistical model to account for the difference in distributions of poverty data between Butte and NHANES.

Table 14: Weights for NHANES Based on Estimated Butte Poverty Distribution

Poverty Category	Year group	Weight*
PIR ≤1.75	2003-2004	1.3
PIR >1.75		0.14
PIR ≤1.75	2005-2006	1.3
PIR >1.75		0.11
PIR ≤1.75	2007-2008	1.5
PIR >1.75		0.15
PIR ≤1.75	2009-2010	1.8
PIR >1.75		0.19

*These weights assume that 95 percent of the Butte sample falls in the PIR ≤1.75 category; Weight - ratio of Butte to NHANES counts
PIR ≤1.75 corresponds to greater poverty, while PIR >1.75 corresponds to lesser poverty.

4.3.3 Selection of Final Variable Weights for Inclusion in the Model

Variable weights evaluated in section 4.3.2 support prioritization of NHANES weighting for the following variables: race/ethnicity, year house built, and poverty category. The year the house was built was considered the most significant variable with respect to affecting BLLs given the proportion of the Butte study population living in homes built while lead paint and lead pipe were still commonly in use. Therefore, the following four weighting scenarios were examined:

1. year house built weighting only;
2. year house built weighting combined with poverty weighting;
3. year house built weighting combined with race/ethnicity weighting; and
4. a combination of weighting for year house built, race/ethnicity, and poverty.

The first step in calculating weights was to determine, for each weight scenario, how frequently different "bins" of data occurred in each dataset (Butte and NHANES). For the weighting scenario that included only house age, bins represented the different year house built categories (e.g., pre-1940, 1940-1949, etc.). For the other weighting scenarios, bins represented every combination of variable categories. For example, for the weighting scenario combining poverty, race, and year house built, a single bin might be represented as the frequency of all records defined by the poverty category for PIR >1.75, the non-Hispanic white race category, and the pre-1940 year built category. Once the frequencies of records for all bins were determined, final weights were calculated as the ratio of the Butte frequencies to the corresponding NHANES frequencies. The final weights were then applied to the NHANES data in the model using standard statistical procedures in SAS (defining a weight variable). Since this effort was undertaken to match the NHANES records more closely to the Butte records, the Butte data is un-weighted which is equivalent to each Butte record having a weight of one. Thus, if the final weights of the NHANES records are added across all the NHANES records in the dataset, the sum equals the count of records in the Butte blood lead database.

The four weighting scenarios were evaluated in the fully adjusted model as described below.

4.3.4 Building the Fully Adjusted Model and Examination of Interaction Terms

Incorporating the significant variables from the univariate analysis that were available in both datasets, the fully adjusted model was built to examine the association between each independent variable and the geometric mean BLL while simultaneously controlling for the other independent variables that may be affecting blood lead. Child test age, child gender, child year house built, test year, test season, and source (Butte or NHANES) were all included in the model. This model used a weighted regression. Weighted regression treats the weight as a multiplier for the record so that a record with a weight of X is treated as if X identical records existed in the dataset. All Butte records have a weight equal to one. The model was repeated for each the four NHANES weighting scenarios described in section 4.3.3 and the preferred scenario was selected.

After choosing the preferred weighting scenario and examining the fully adjusted model results, interaction terms were also added to the model and examined. The addition of an interaction term to a model helps to tell whether the relationship between two variables, such as BLL and test year, varies according to a third variable, such as source (NHANES or Butte). In this example, the source and test year represent two variables that can be included as an interaction term in the model.

Results of the fully adjusted model including selection of the final weighting scenario are presented below.

4.3.4.1 Fully Adjusted Model without Interaction Terms

The fully adjusted model was run using each of the four weighting scenarios to determine how each scenario changed the geometric mean BLLs from the original un-weighted data (Figure 11). When the NHANES data were weighted to match Butte on house age and poverty (scenario 2), the resulting geometric mean BLLs were higher than the un-weighted data. This weighting scenario emphasizes the children in NHANES who have higher poverty and who live in homes more likely to contain sources of lead. When the combination of all three variables was used (scenario 4), the geometric mean BLLs generally dropped. Adding race to the weighting (scenarios 3 and 4) emphasizes the white population in NHANES, who typically have lower BLLs than the other races. Ultimately all three variables (scenario 4) were used to weight NHANES because they were all significantly different between Butte and NHANES and when they were combined, they didn't appear to significantly skew the NHANES data in one direction.

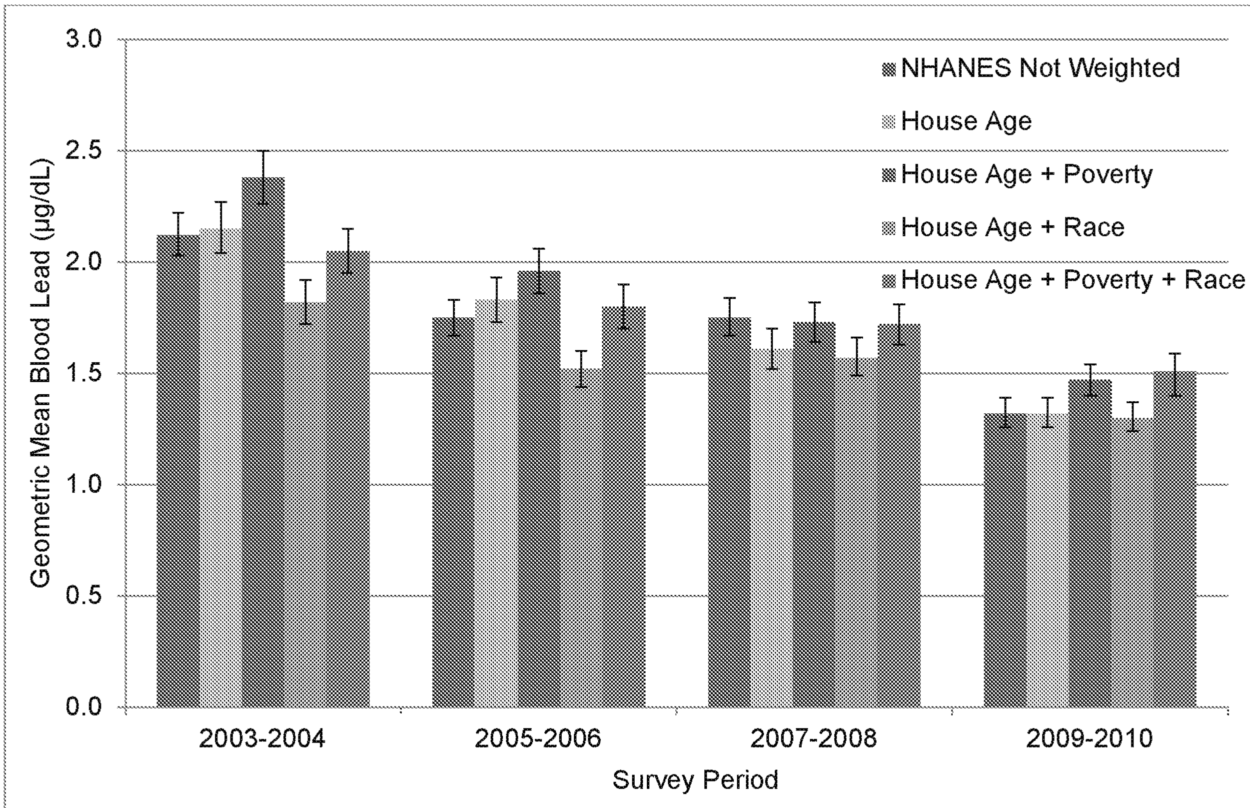


Figure 11: Geometric Mean and 95% Confidence Intervals Comparing Four NHANES Weighting Scenarios and NHANES without Weights (from Butte vs. NHANES Stratified Model) with 95% Confidence Intervals

In the fully adjusted model with NHANES weighted for house age, poverty, and race, all data from Butte and NHANES (after weighting) were combined to determine if differences between these two datasets could be detected statistically. Table 15 summarizes the initial results of the fully adjusted model without inclusion of any interaction terms. For this model, child test age was treated as a continuous variable and all other independent variables as categorical.

Table 15: Results from Full Linear Mixed Model Combining Butte and NHANES Datasets

Variable	GM/Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p value
Child test age (estimate)	0.94	0.93	0.96	<0.0001*
Child gender				
Female	2.02	1.95	2.09	0.083
Male	2.07	2.00	2.13	Reference
Source				
Butte	2.34	2.27	2.42	<0.0001*
NHANES (adjusted)**	1.78	1.73	1.84	Reference
Year house built				
Missing	2.02	1.96	2.09	<0.0001*
Post 1977	1.63	1.49	1.78	<0.0001*
1960 to 1977	1.92	1.78	2.07	<0.0001*
1950 to 1959	1.98	1.84	2.14	<0.0001*
1940 to 1949	2.14	2.02	2.27	<0.0001*
Pre1940	2.71	2.63	2.79	Reference
Test year				
2003-2004	2.68	2.57	2.79	<0.0001*
2005-2006	2.20	2.11	2.29	<0.0001*
2007-2008	1.95	1.87	2.03	<0.0001*
2009-2010	1.52	1.46	1.57	Reference
Test season				
Winter/Spring	1.83	1.77	1.89	<0.0001*
Summer/Fall	2.28	2.21	2.35	Reference

*Statistically significant ($p \leq 0.05$)
**NHANES data are weighted by race, poverty, and house age
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit-less.

After accounting for differences in test year, year house built, test season, child gender and child test age, over all test years, the geometric mean in Butte of 2.34 µg/dL was significantly higher than the geometric mean of 1.78 µg/dL in NHANES ($p<0.0001$).

4.3.4.2 Examine Interaction Terms

Because a primary aim of the study was to determine if BLLs changed differently over time in Butte compared to NHANES, an interaction term for test year and source was added to the model.

When this interaction term was included in the model, it was found to be significant ($p < 0.0001$). In order to explore this interaction, the model was stratified by source, allowing for comparisons between Butte and NHANES according to the other variables in the model.

4.3.5 The Final Model (Stratified by Source – Butte vs. NHANES)

The final statistical model for the Butte vs. NHANES comparison was stratified by source (Butte vs. NHANES) to examine the influence of each of the remaining independent variables on BLL for Butte compared to NHANES. To determine whether the rate of decline in BLLs over time is different in Butte than NHANES, the coefficients and standard errors for test year (treated as a continuous variable) from the Butte adjusted model and the NHANES adjusted model were used to calculate a Chi-squared test statistic. This test statistic with one degree of freedom was then compared to the Chi Square distribution to determine if the null hypothesis that the coefficients were the same could be rejected at a significance levels of $\alpha = 0.05$.

4.4 Butte vs. NHANES Comparison Model Results

Table 16 summarizes the results of the final stratified model for the Butte vs. NHANES comparison. For both the Butte dataset and the NHANES dataset, model-generated geometric mean BLLs and confidence intervals are presented. The influence of each independent variable (i.e., test year, house age, child test age, child gender, or test season) on BLL is presented after adjusting for the influences of all the other variables. Confidence intervals may be compared, across each variable category for Butte and NHANES to provide an indication of whether geometric mean BLLs for each source are statistically different. However, additional statistical comparisons of results for Uptown and the Flats were performed using a t-test with p values comparing groups also shown in Table 16.

Table 16: Final Results for Butte vs. NHANES Model Stratified by Source

	Butte				Adjusted NHANES**				Comparison‡
Variable	GM/ Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p Value	GM/ Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p Value	p Value
Child test age (estimate)	0.97	0.94	0.99	0.0040*	0.92	0.90	0.94	<0.0001*	0.0006*
Child gender									
Female	2.22	2.11	2.34	<0.0001*	1.80	1.73	1.87	0.056	<0.0001*
Male	2.51	2.38	2.64	Reference	1.72	1.65	1.79	Reference	<0.0001*
Year house Built									
Missing	2.5	2.38	2.62	<0.0001*	1.65	1.59	1.72	<0.0001*	<0.0001*
Post 1977	1.84	1.6	2.11	<0.0001*	1.45	1.30	1.61	<0.0001*	0.011*
1960 to 1977	2.25	2	2.54	<0.0001*	1.63	1.48	1.79	<0.0001*	<0.0001*
1950 to 1959	2.36	2.09	2.67	<0.0021*	1.67	1.53	1.83	<0.0001*	<0.0001*
1940 to 1949	2.45	2.23	2.69	<0.0016*	1.84	1.70	1.98	<0.0001*	<0.0001*
Pre1940	2.9	2.77	3.04	Reference	2.47	2.37	2.57	Reference	<0.0001*
Test year									
2003-2004	3.48	3.26	3.72	<0.0001*	2.05	1.95	2.15	<0.0001*	<0.0001*
2005-2006	2.65	2.48	2.83	<0.0001*	1.8	1.70	1.90	<0.0001*	<0.0001*
2007-2008	2.2	2.06	2.35	<0.0001*	1.72	1.63	1.81	<0.0001*	<0.0001*
2009-2010	1.53	1.44	1.63	Reference	1.51	1.44	1.59	Reference	0.89
Test season									
Winter/Spring	2.13	2.03	2.24	<0.0001*	1.56	1.48	1.66	<0.0001*	<0.0001*
Summer/Fall	2.62	2.49	2.75	Reference	1.98	1.91	2.06	Reference	<0.0001*

*Statistically significant ($p \leq 0.05$)
**NHANES results are weighted for house age, poverty, and race
‡p value comparing GM in NHANES to the GM in Butte
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit-less.

By source, BLL trends are generally similar for Butte and NHANES except for child gender. General trends common to both groups include:

- lower BLLs in the most recent study periods;
- higher BLLs for children aged 12 to 35 months at the time the test was taken than for children aged 36 to 60 months;
- lower BLLs when tested in the winter/spring than in the summer/fall season; and
- higher BLLs for children living in older homes.

For gender, Butte has lower BLLs in females than males. The opposite is true for NHANES, with females having higher BLLs than males.

Across source, in the adjusted model, geometric mean BLLs in Butte are significantly higher than in NHANES for all house age categories, in both the summer/fall and winter/spring, and in both males and females. BLLs decline with an increase in child's age at testing in both populations, but the decline in Butte (3 percent) is lower than in the NHANES population (8 percent). Significant declines in BLLs over time (i.e., with increasing test year) were evident for both populations. For 2003-2004, 2005-2006, and 2007-2008, geometric mean BLLs were higher for Butte than for NHANES (Figure 12). However, for 2009-2010, the means are not significantly different, suggesting that the decline in BLLs has been faster in Butte over the study period. By 2009-2010, controlling for the influence of all other variables, the geometric mean BLL for Butte was 1.53 µg/dL, compared to 1.51 µg/dL for NHANES. The p value confirmed that the difference was not significant for this test period (p=0.89).

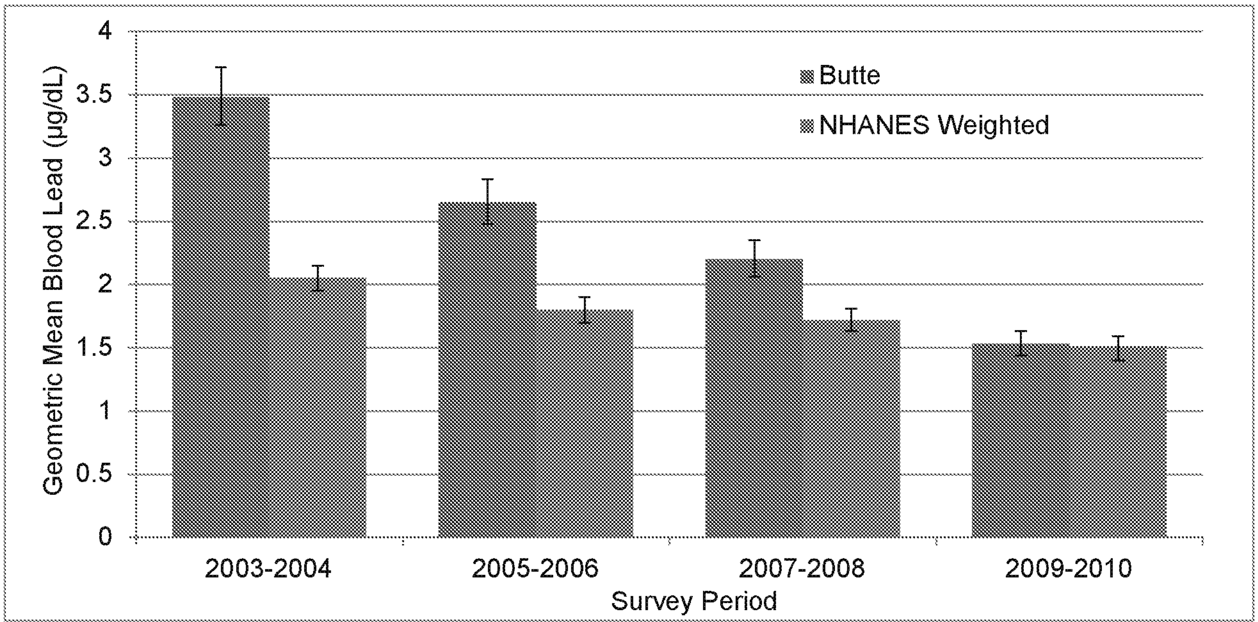
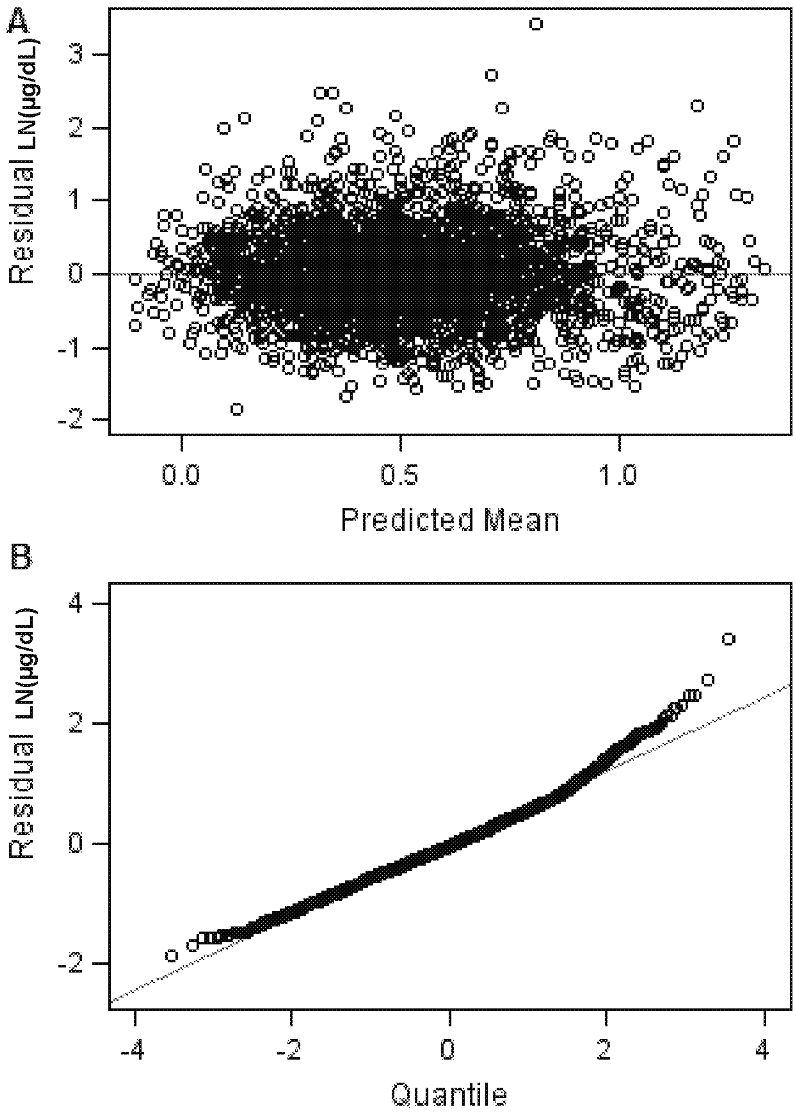


Figure 12: Modeled Geometric Mean Blood Lead Levels for Butte Compared to the Adjusted NHANES Data by Test Year with 95% Confidence Intervals

The Chi-squared test further confirmed that the rate of BLL decline from 2003 through 2010 is statistically greater for Butte than it is for NHANES (p<0.0001). In Butte, geometric mean BLLs have declined by 24 percent over each two-year period while in NHANES BLLs have declined by 9 percent.

Residual plots of the NHANES and Butte data from the final stratified model were generated to examine how well the model fit the data (Figure 13 and 14). A model with a good fit is more likely to accurately predict the geometric mean BLLs. Residuals are the difference between the model-predicted BLLs and the BLLs from the raw data. The BLLs that the model predicts should not always be higher than or lower than the BLLs from the raw data. Such a skew in the residuals would suggest a poor fitting model and would show up in the residuals plot as having a pattern (e.g., a majority of the residuals would be negative) vs. being randomly distributed. For a good fitting model, the residuals should be distributed randomly, without a clear pattern.

Figure 13A and 14A show a random distribution of residuals around the predicted mean for the weighted NHANES dataset and the Butte dataset, respectively. The general alignment with residuals along the quantile (Figure 13B and 14B) also suggests the model is a decent fit for the weighted NHANES dataset and the Butte dataset, respectively. The tails of the plot in Figure 13B lift slightly from the quantile suggesting that there is still a mild right skew to the data after log transformation. However, the mild skew is not expected to substantially alter the results.



Data are log transformed prior to analysis. Data have been weighted by house age, poverty, and race.

Figure 13: Residuals Plots for the NHANES Blood Lead Levels from the Butte vs. NHANES Stratified Model

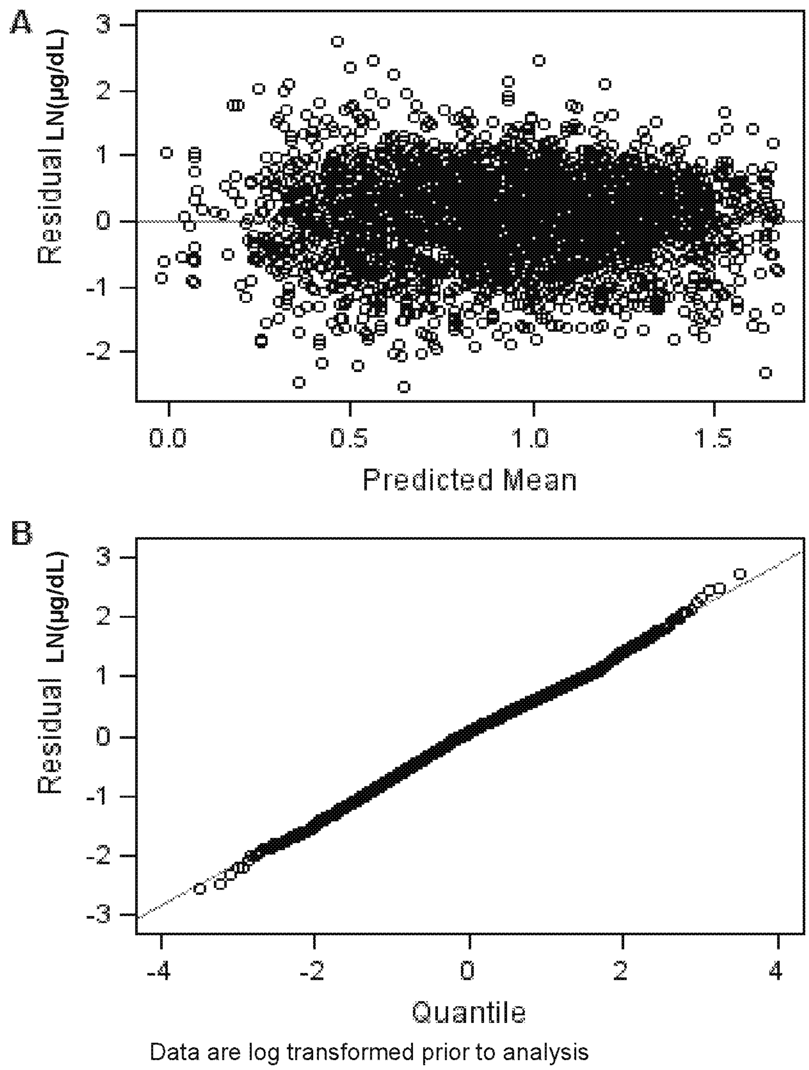


Figure 14: Residuals Plots for the Butte Blood Lead Levels from the Butte vs. NHANES Stratified Model

4.5 Summary and Conclusions

Development of the Butte vs. NHANES statistical model allowed for the comparison of BLLs (the dependent variable) between the Butte and NHANES sample populations, while accounting for other independent variables that can influence blood lead but may not be unique to either population. Key variables influencing BLLs that were considered during model development included gender, child age, test year, race, poverty level and house age. Tests using univariate statistics confirmed that all of these variables had significant associations with BLLs. Model development considered all variables in building a fully adjusted model and then interaction terms. Because many children in Butte have repeated BLL measurements, linear mixed models were used to account for the correlated nature of those data.

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A key step was development of weighting factors to determine how the statistical distribution of NHANES values for each variable differed from the distribution of that variable within the Butte dataset. Based on this analysis, it was determined that the full model did not need to include weighting factors for child gender, child age, test year or test season because the two datasets were similar with regard to the distribution of these factors. In contrast, race, poverty level, and house age were all determined to be variables for which weighting factors were needed to support the population comparison. The weighting scenarios for these three variables were compared to determine how they changed the geometric mean BLLs for NHANES from the original un-weighted NHANES data. Ultimately, a combination of all three variables was used to weight NHANES because the distribution of each was substantially different between Butte and NHANES, and it was important to ensure that the overall weights reflected the influence of each variable on BLLs.

The final statistical model for the Butte vs. NHANES comparison was stratified by source (Butte vs. NHANES) to examine the influence of each of the remaining independent variables (test year, child test age, child gender, year house built, and test season) on BLL for Butte compared to NHANES. Additionally, a Chi-squared test was used to examine the rate of BLL decline for Butte compared to NHANES. Based on t-tests, BLLs in Butte are significantly higher than in NHANES for all variable categories except for children tested in 2009-2010. In both populations, BLLs declined over time during the study period. For 2003-2004, 2005-2006, and 2007-2008, geometric mean BLLs were higher for Butte than for NHANES. However, for 2009-2010, the means were not significantly different. Controlling for the influence of all other variables, the geometric mean BLL for Butte during 2009-2010 was 1.53 µg/dL compared to 1.51 µg/dL for the adjusted NHANES dataset.

The final model indicates that based on examination of geometric mean BLLs and confidence intervals, Butte BLLs exceeded those from the reference population from 2003 through 2008. However, due to a greater rate of decline in Butte BLLs over time, Butte BLLs no longer exceeded those of the reference population during the 2009-2010 period. The specific factors causing the higher rate of decline in Butte BLLs cannot be determined based on this analysis, but such factors could include ongoing RMAP response efforts. It should also be noted that some factors known to be associated with BLLs could not be accounted for in this study (for example, maternal education).

One way to evaluate the extent to which factors other than the Butte environment may be influencing BLLs for the study population is to look at how well the adjusted NHANES dataset compares to the NHANES data on which the current CDC blood lead reference value, 5 µg/dL, is based. The CDC reference value represents the 97.5th percentile of BLLs for the national population of children ages 1 to 5 based on children surveyed from 2005-2006 and 2007-2008. For the current study, NHANES data for these same survey periods were adjusted to make the NHANES population more similar to the Butte study population with regard to racial composition, poverty threshold, and residential make-up of house ages for children tested. These variables were selected for weighting NHANES data in the statistical model due to their importance as risk factors for elevated BLLs and because the distributions of data for each variable differed most from the corresponding Butte distributions. Thus, the adjusted NHANES data for 2005 through 2008 represent the national population of children surveyed with emphasis on BLLs for those whose demographic characteristics are most similar to the Butte study population. In contrast to the reference value, which is based on 2.5 percent of national children with BLLs greater than 5 µg/dL, when these same national data are adjusted to create a reference population that better matches the Butte study population demographics, the proportion of children in the reference population with BLLs greater than 5 µg/dL is much higher (10.3 percent adjusted reference population vs. 2.5 percent unadjusted, national population). This finding highlights the importance in the current study of adjusting for the potential influence of race and other socioeconomic risk factors associated with elevated BLLs when comparing the Butte blood lead data to blood lead data from a reference population.

5 Butte Neighborhood Comparison

As described in section 1, two lines of evidence are evaluated in this study to address the principal study question. The second line of evidence looks at whether statistically significant differences in BLLs across Butte neighborhoods, measured in conjunction with the RMAP, are reduced relative to differences documented in pre-RMAP BLLs across Butte neighborhoods. RMAP activities have been conducted throughout the study period, 2003-2010. Blood lead data reflecting pre-RMAP exposures within Butte are available from a 1990 exposure study conducted by the BSB Health Department and the University of Cincinnati (BSBHD/UC 1992). The 1990 exposure study identified statistically significant differences across selected areas of Butte that were related to house age and proximity to mining sources. These findings led the investigators to recommend development of a program in Butte to identify and address residential lead exposures from all sources, even though BLLs in Butte at that time were not found to be elevated relative to national data (BSBHD/UC 1992).

The current RMAP and its predecessor programs in Butte arose out of the 1990 exposure study recommendation and have been actively seeking to reduce residential exposures since about 1994. Blood lead data collected via RMAP were not collected in a similar manner or for the same purpose as the 1990 exposure study, thus the current study not intended to reproduce the 1990 exposure study. However, looking at whether or not differences in BLLs still exist across different areas of Butte and in association with variables, such as house age and proximity to mine sources, provides information that can be used to assess whether the RMAP has been effective in reducing exposures to lead across Butte and whether there are elements of the program that might be revisited to better identify and reduce residential exposures in Butte.

A brief summary of the 1990 exposure study is provided below. The remainder of this section describes the Butte neighborhood comparison model development and results. Supplemental analyses are also presented along with a summary of overall conclusions from the Butte neighborhood analysis.

5.1 Summary of the 1990 Exposure Study

The 1990 exposure study evaluated child BLLs across seven distinct Butte neighborhoods (Areas A-G; Figure 15). The number of children tested within each neighborhood ranged from 11 to 183. Blood lead results for all age groups tested in Butte in 1990 are summarized in Table 17.

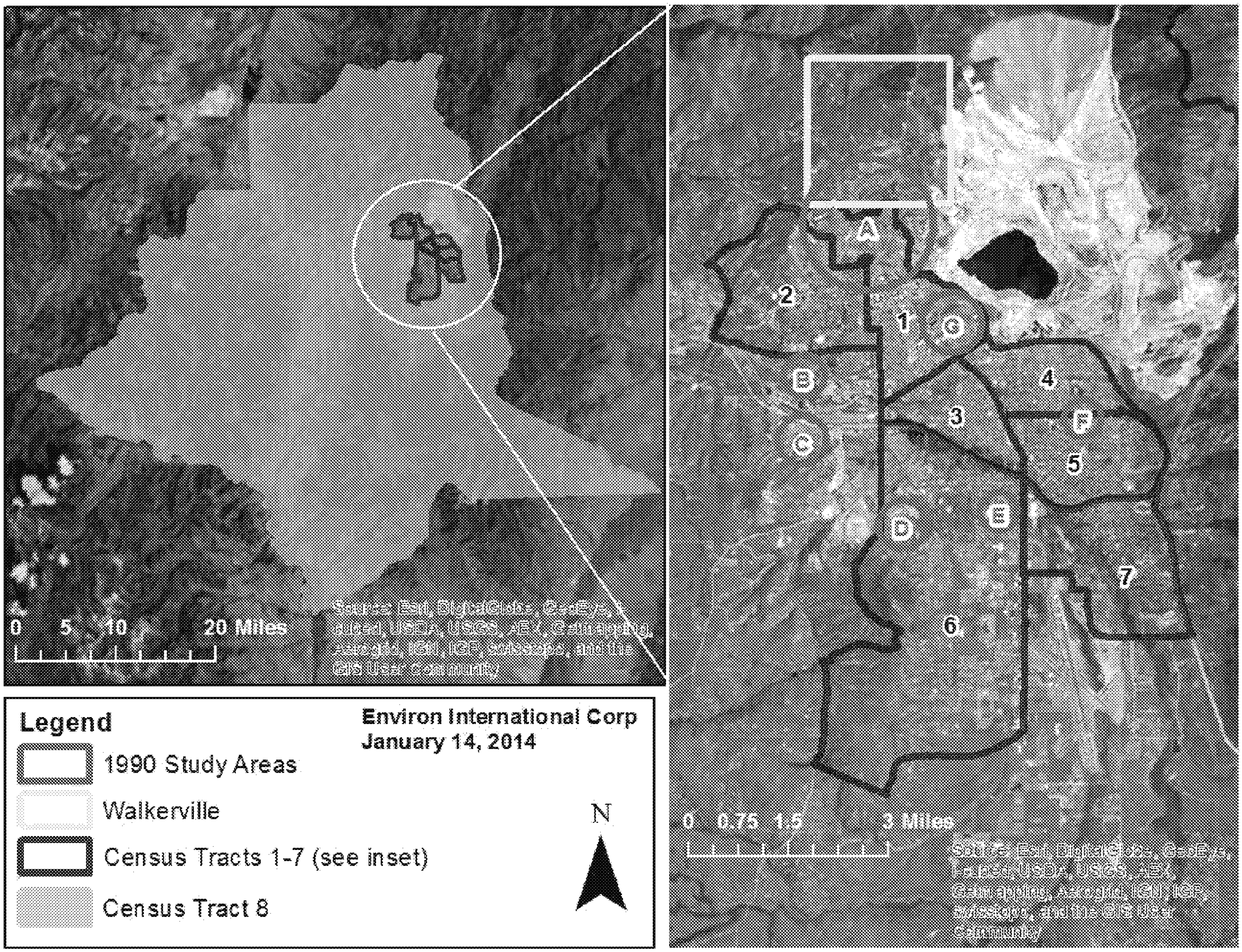


Figure 15: Map of Butte Showing Census Tracts and 1990 Study Areas (BSBDH/UC 1992)

Table 17: Blood Lead Results Reported in 1990 Butte Exposure Study

Statistic	1990 Butte Blood Lead					
	< 72 months*	72 months to 18 years	Adults	Nursing Women	Pregnant Women	All
Sample Size	294	53	48	11	24	430
Geometric Mean (µg/dL)	3.5	3.5	3.1	2.4	2.1	3.4
GSD (µg/dL)	1.8	1.8	1.9	1.6	1.5	1.8
95^{th} Percentile (µg/dL)	10.5	13.6	10.3	5.0	3.3	9.5
Maximum (µg/dL)	25.0	18.0	12.0	5.0	3.5	25.0

GSD- Geometric standard deviation
*Includes infants <12 months old

The study investigators reviewed available soil contamination data for Butte and met with the BSB Health Department to identify neighborhoods likely to show the widest range of exposures to lead from different sources. A comprehensive door-to-door recruitment effort was conducted to identify study participants from the general Butte population.

For each neighborhood, the factors potentially influencing BLLs were characterized and included house age, the likelihood of lead paint and lead pipe presence, and the potential for exposure to waste rock or mill tailings within the community (e.g., the Berkeley Pit, Colorado Tailings, Montana Pole Site, and Clark Tailings). Table 18 summarizes the neighborhood characterizations presented in the 1990 exposure study along with blood lead statistics for the children tested. Each of the seven neighborhood areas selected for the 1990 study (Areas A through G) was among the oldest neighborhoods in Butte.

Table 18: Blood Lead Results for Children <72 Months by Neighborhood in 1990 Butte Exposure Study

	1990 Butte Study Areas						
	Area A	**Area B**	**Area C**	**Area D**	**Area E**	**Area F**	**Area G**
Lead Exposure							
Exposure to Waste Rock or Mill Tailings	High	Medium	Medium	Medium	Low	Low	High
Presence of Lead Paint	High	Low	Medium	High	Medium	Medium	High
Presence of Lead Pipe	High	Low	Medium	Medium	Medium	Medium	High
Blood Lead Statistics*							
Number of Participants	183	15	12	11	27	17	13
Geometric Mean (µg/dL)	3.7	2.3	4.6	4.6	2.7	3.0	3.8
GSD (µg/dL)	1.8	1.7	1.9	1.8	1.5	1.5	1.7
95^{th} Percentile (µg/dL)	10.9	4.0	14.5	22.5	5.6	6.5	8.0
Maximum (µg/dL)	25.0	4.0	14.5	22.5	6.0	6.5	8.0
Property Perimeter Soil Lead							
Number of properties	145	10	7	9	21	12	11
Geometric Mean (ppm)	750	250	139	234	151	178	1031
Property Non-Perimeter Soil Lead							
Number of properties	135	9	7	9	19	12	10
Geometric Mean (ppm)	699	358	154	209	136	147	626

*The study also reports on 15 children less than 72 months that were outside of the study areas.
GSD- Geometric standard deviation; ppm – parts per million

The highest average BLLs occurred in Areas A, C, D, G, which were all characterized as medium or high for exposure to waste/tailings and likely presence of lead paint and lead pipe. Specifically, area A was in an area defined by EPA as a "Soil Priority Area," had houses built as early as 1886, and included railways used to transport ore, as well as waste rock dumps, giving it a "high" classification for all exposure routes (waste rock, lead paint, and lead pipe). Area C was not in an EPA Soil Priority Area, however, it was within 1,000 feet of Colorado tailings piles and the historic Colorado smelter site (representing a "medium" exposure level to waste/tailings). The houses in this area were built between 1930 and 1970. Area D was in an EPA Soil Priority Area, was within 1,000 feet of the Clark tailings and former mill, and had houses built in the same time period as Area C. Area G, like Area A, had a "high" classification for all exposure routes given that the houses were built between 1891 and 1930 and that it was also surrounded by railways and historic mining sites.

The 1990 exposure study included environmental samples (i.e., yard soil, dust, tap water, lead paint), as well as blood lead samples. Table 18 shows geometric mean blood lead for children in the study and perimeter and non-perimeter soil lead concentrations for each area. Study investigators used the blood lead data and the environmental data to develop a structural equation model of lead exposure pathways. This analysis showed that residence location (i.e., neighborhood area) and house age were the strongest predictors of paint lead, soil lead, and dust lead concentrations. Lead-based paint was shown to be associated with lead contaminated soil, which was in turn associated with lead contaminated house dust. Only house dust lead was directly related to blood lead. The indirect effect of soil lead on blood lead was shown to be both small and weak. The investigators concluded that 39 percent of the variability in soil lead concentrations was attributable to lead-based paint, while the remainder (61 percent) was attributable to "the heterogeneous distribution of lead in soil, and lead from other sources such as native lead in soil, mine waste, and contaminates from ore processing." Gardening or eating home grown produce was shown not to contribute to elevated BLLs.

Based on the findings of this study, the University of Cincinnati investigators, Dr. Bornschein and Dr. Clark, recommended to the BSB Board of Health that a blood lead surveillance and abatement program be established in Butte (June 5, 1991 letter included in the 1992 report). The predecessor to the RMAP was implemented in response to these recommendations. The findings of this study also provided site-specific data used by EPA in their health risk assessment and cleanup goal development.

5.2 Delineation of Butte Neighborhoods for the Current Study

As described in section 2, more than 3,000 blood lead records are available to assess eight years of Butte child BLLs as compared to a single year evaluated in the 1990 exposure study. The recent Butte data were collected from individuals living in and around the 1990 exposure study areas but are not specifically aligned with those areas. Spatially, the recent data correspond to individuals tested throughout all eight census tracts of Silver Bow County, with the majority of the data encompassed by Census Tracts 1 through 7 and Walkerville, which cluster around the central urban area of Butte. The remainder of Census Tract 8, excluding Walkerville, surrounds this central cluster and extends outward to the more rural perimeters of the county (Figure 15).

Many of the specific mine waste and tailings exposure sources considered during neighborhood selection for the 1990 study have been addressed since that study was conducted, resulting in the reduction or elimination of pathways for exposure to those sources. However, the distribution of recent blood lead data still varies in proximity to active and historical mining areas where contamination still represents a potential for increased exposures relative to areas of Butte more distant from these sources. Based on available census data, house ages (i.e., year built data) and poverty status also vary across different Butte census tracts. Given the abundance of recent data available throughout Butte and the variability across different areas of Butte with regard to factors that might influence BLLs, delineation of neighborhoods for the current study was not limited to areas studied in 1990.

For the current study, the recent blood lead data were first split according to census tracts. The Butte blood lead dataset from the BSB Health Department had limited socioeconomic and demographic data associated with it. However, census data can provide a general indicator of population characteristics for different areas, including data on racial composition, median family income, percent below poverty level, house age group, and population age structure. Census block data were also investigated but found to be more limited than census tract data with regard to the types of summary data that were available. While census data are useful, differences between individuals represented in the census data population and in the Butte blood lead data population are expected. For example, recruitment of many of the individuals represented in the Butte blood lead database is likely to have selected for individuals from the WIC-eligible population. These individuals are likely to have greater poverty and live in the oldest housing in Butte.

The majority of the data points fell within Census Tracts 1-7, with very sparse data in Tract 8 (except for Walkerville). Census Tract 8 encompasses rural areas and is significantly larger than the other tracts combined (Figure 15). Several participants' homes within Census Tract 8 are located near the boundaries of Census Tracts 1-7. For these houses, satellite imagery showing the layout of roadways and clustering of houses was assessed to judge whether these Tract 8 houses appeared to be distinct neighborhoods or proximal extensions of neighborhoods associated with other tracts. A distance of approximately 500 meters around Census Tracts 1-7 was found to encompass many of the Census Tract 8 homes that appeared to be part of the same neighborhoods as the other tracts. Using geospatial analysis tools, a 500 meter buffer was applied to the outer perimeter of Census Tracts 1-7 to capture the proximal Census Tract 8 houses (Figure 16). Applying this buffer, blood lead data for individuals residing within neighboring houses were grouped with data from other residential areas that are likely to share similar characteristics (e.g., house age, socioeconomic level, etc.) and proximity to common sources of lead within the local environment.

Neighborhoods N1 through N7 were then delineated for the statistical model based on the addition of records captured from Census Tract 8 in the buffer around Census Tracts 1 through 7, respectively. The only exception to the applied buffer was at the boundary between Walkerville and the northern border of N1. A significant number of blood lead records are available for the Walkerville area. These records correspond to some of the oldest homes in Butte (dating back to 1875), where the likely presence of lead-based paint and lead pipe is expected to be high. Despite the smaller population of Walkerville, more properties have been sampled for metals and abated there than in neighborhoods N3 through N7 combined. Additionally, this community sits at a higher elevation than the majority of Butte, distinguishing it geographically from the rest of the study area. Given this, a decision was made to delineate Walkerville as a separate neighborhood (N8) from all other neighborhoods in the statistical model. Seventy-nine data points that fell both in the 500 meter buffer of Tract 1 and in the Walkerville boundary were assigned to N8. Additionally, 30 data points that fell just south of Walkerville but within the N1 buffer area were also reassigned to N8 based on input from the Working Group.

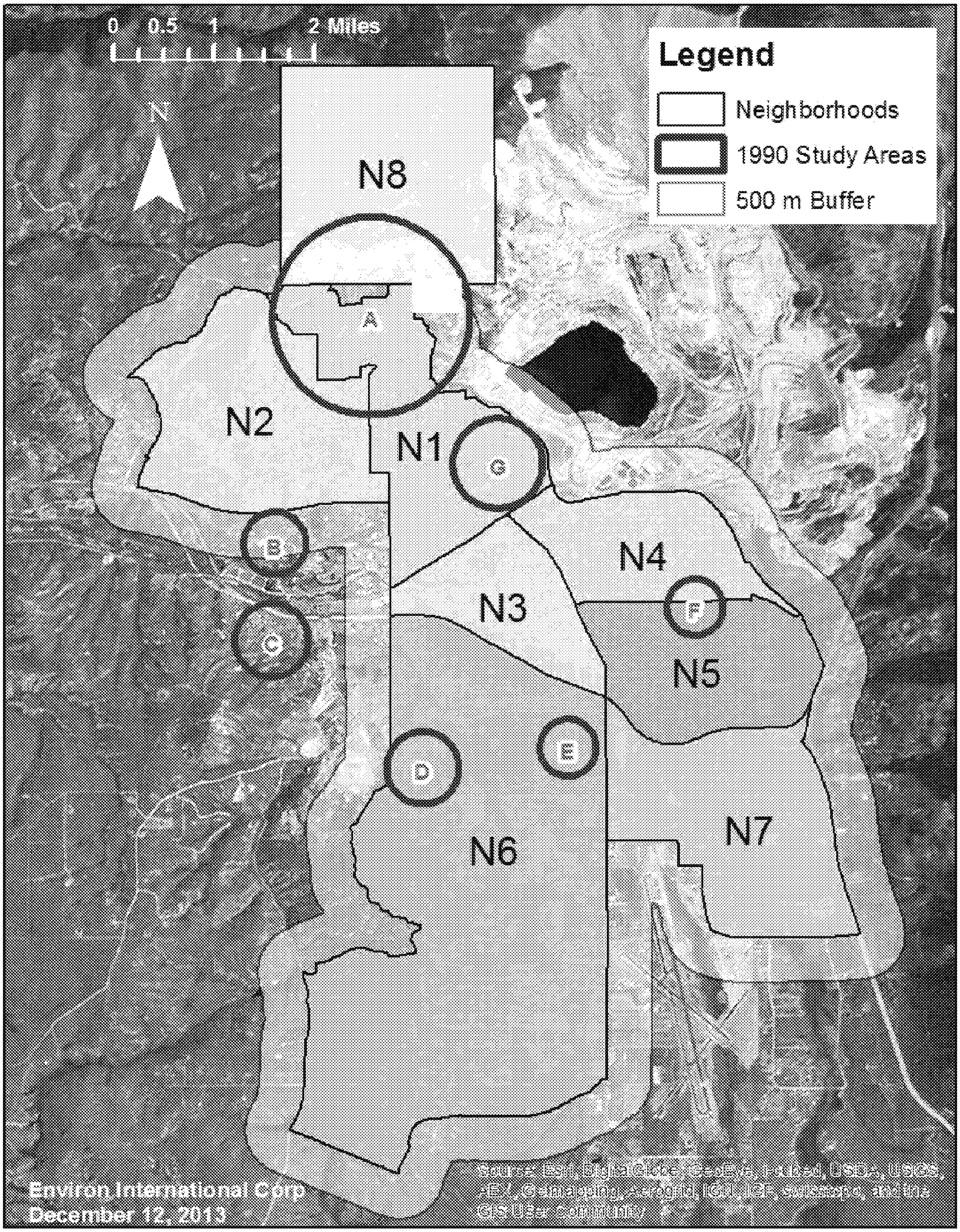


Figure 16: Map of Butte Showing 500 Meter Buffer around Census Tracts and 1990 Study Areas (BSBDH/UC 1992)

For blood lead records between 2003 and 2010, 72 records from 41 houses within Census Tract 8 that were not encompassed by neighborhoods N1 through N8 were excluded from the statistical model for the Butte neighborhood comparison given that these blood lead records were not clustered together or proximal to the other eight neighborhoods delineated. However, these 72 records were included in the statistical comparison of Butte blood lead data to the reference blood lead dataset (section 4). Summary statistics for these data are included in Table 19.

Table 19: Summary Statistics for 72 Blood Lead Records Excluded from the Butte Neighborhood Comparison

Statistic	Mean	SD	Median	Minimum	Maximum
BLL (µg/dL)	2.3 (GM)	2.3 (GSD)	2.7	<1	17.4
Age (years)	2.6	1.1	2.4	1	4.8

GM – Geometric mean; SD – Standard deviation; GSD - Geometric standard deviation

For the 2003 through 2010 time period, a total of 2,724 blood lead records are available for neighborhoods N1 through N8 combined. An additional 452 records are also available from 2011. The 2011 records were used to confirm BLL declines in one statistical model as well as for supplemental analyses in section 5.5. Sample sizes by neighborhood and year are shown in Table 20. The locations of neighborhood study areas evaluated in 1990 are shown in comparison to neighborhoods N1 through N8 in Figure 16.

Table 20: Sample Size by Neighborhood and Year for 2003 through 2011

Year	N1	N2	N3	N4	N5	N6	N7	N8	Total
2003	102	40	32	51	29	69	4	16	343
2004	79	42	38	44	21	61	7	16	308
2005	84	29	27	41	18	79	12	13	303
2006	76	35	37	30	27	84	14	16	319
2007	83	50	33	49	26	72	17	7	337
2008	93	56	21	31	24	66	17	11	319
2009	96	49	26	56	30	71	13	11	352
2010	121	55	37	63	39	93	13	22	443
2011*	131	64	42	57	31	97	15	15	452

*2011 data were only used in models to confirm trends seen in prior years and used outside of the model for supplemental analyses.
N1 – Neighborhood 1

5.3 Butte Neighborhood Model Development

The Butte neighborhood analysis necessitated development of a statistical model that allowed for comparison of BLLs (the dependent variable) from children 12-60 months of age for neighborhoods N1 through N8 while accounting for other independent variables that can influence BLLs (factors described in section 3). The software used to perform these statistical analyses was SAS Version 9.3 (SAS Institute Inc., Cary, NC).

Because many children in Butte have repeated BLL measurements, linear mixed models were used to account for the correlated nature of the data. The “MIXED” procedure in SAS was used because it is able to handle repeated/correlated data, as well as data with a different number of measurements per subject. When using the “MIXED” procedure, a covariance structure or specification about how the measurements are related over time was chosen. For the Butte neighborhood analysis, an autoregressive covariance structure was used, meaning that measurements farther apart in time are assumed to be less correlated than observations closer in time. The SAS “MIXED” procedure provides F-tests from the “Type 3 Tests of Fixed Effects” which were used to determine the overall significance of variables, as well as partial t-tests from the “Solution for Fixed Effects” which were used to determine the significance of the different levels/categories of each variable compared to a reference. When multiple comparisons were made, Tukey’s multiple comparison tests were applied. Additionally, a Least Squares Means (LSMEANS) statement was used to calculate geometric means and 95 percent confidence intervals for all categorical variables.

The first step of the model development was generating the univariate statistics. The univariate statistics examined each independent variable individually to determine whether it influenced the dependent variable: the BLLs.

Based on the results from the univariate analysis, a fully adjusted multivariable model was built. In the fully adjusted model, the effect of each independent variable on BLLs was examined after adjusting for all of the other variables included in the model. An *a priori* decision was made that all variables that were significant ($p<0.05$) in the univariate analysis would be included in the fully adjusted model. Interaction terms of interest were then added to the fully adjusted model. Finally, the fully adjusted model was stratified, first by neighborhood (N1–N8) and then by two groupings of neighborhoods. This section describes the process and information used to develop the final stratified statistical model.

5.3.1 Identification of Significant Variables for Inclusion in the Model

The first step in building the Butte neighborhood comparison model involved identifying which independent variables to include in the model. A univariate statistical analysis was conducted to evaluate the significance of several independent variables with regard to their individual influence on blood lead. Table 21 summarizes the details for each variable examined and the results of the univariate analyses. For each variable examined in the univariate analysis, estimates and p values from t-tests, as well as geometric means and 95 percent confidence intervals around the means were calculated. The estimates do not have units,[15] while the geometric mean of BLLs and confidence intervals have units of µg/dL.

From Table 21, the statistically significant p value for child test age (a continuous variable) means that as child test age increases, the BLLs decrease (p=0.0033). The p values for the categorical variables compare each category within that variable to a reference category. In general, the category with the largest sample size was chosen as the reference for each variable examined. For these estimates, the p value shows whether the BLLs for a given category are significantly different from the reference. For instance, the BLLs in neighborhoods N3, N4, N5, N6, and N7 are significantly lower than those in neighborhood N1 (Table 21). However, there is no evidence to suggest that the BLL in neighborhoods N2 or N8 are different than the BLL in neighborhood N1 (p=0.84 and 0.43, respectively).

[15] Estimates below one represent a decline in BLLs with increasing test year or increasing child test age for those variables, while estimates above one represent an increase in BLLs. An estimate of 0.88 for test year indicates that BLLs are declining 12 percent per year.

Table 21: Results from Univariate Analysis for Butte Neighborhood Comparison					
Variable	**N****	**GM/Estimate (µg/dL)**	**95% LCL (µg/dL)**	**95% UCL (µg/dL)**	**p Value**
Child test age (estimate)	2724	0.96	0.94	0.99	0.0033*
Child gender					
Male	1408	2.69	2.56	2.82	Reference
Female	1316	2.32	2.21	2.44	<0.0001*
Neighborhood					
N8	112	3.10	2.63	3.64	0.43
N7	97	1.91	1.62	2.24	<0.0001*
N6	595	2.12	1.98	2.27	<0.0001*
N5	214	2.18	1.95	2.44	<0.0001*
N4	365	2.34	2.14	2.55	<0.0001*
N3	251	2.51	2.26	2.79	0.020*
N2	356	2.92	2.68	3.19	0.84
N1	734	2.89	2.72	3.07	Reference
Year House built					
Missing	945	2.40	2.27	2.54	<0.0001*
Post 1977	96	1.69	1.43	1.99	<0.0001*
1960 to 1977	152	2.23	1.96	2.54	0.0012*
1950 to 1959	158	2.23	1.95	2.56	0.0019*
1940 to 1949	244	2.39	2.15	2.65	0.0061*
Pre 1940	1129	2.81	2.67	2.95	Reference
Test year					
2003-2004	651	3.80	3.58	4.04	<0.0001*
2005-2006	622	2.89	2.72	3.06	<0.0001*
2007-2008	656	2.44	2.30	2.58	<0.0001*
2009-2010	795	1.71	1.62	1.80	Reference
Test season					
Winter/Spring	1369	2.30	2.20	2.40	<0.0001*
Summer/Fall	1355	2.73	2.61	2.85	Reference

*Statistically significant ($p \leq 0.05$)
**The N differs from the univariate results for Butte presented in Table 5 because it excludes the 72 samples from Census Tract 8 that were not assigned to a neighborhood and were dropped from that analysis.
N – Sample size; GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit.
Estimates are unit-less

An F-test was used to also determine p values for each variable as a whole, not by category, as in Table 21.[16] All significant variables from this F-test were incorporated into the fully adjusted model (Table 22).

Table 22: Results from F-test for All Variables from the Univariate Butte Neighborhood Analysis

Variable	p value from F-Test
Child test age	0.003*
Child gender	<0.0001*
Neighborhood	<0.0001*
Year house built	<0.0001*
Test year	<0.0001*
Test season	<0.0001*

*Statistically significant ($p \leq 0.05$)

5.3.2 Building the Fully Adjusted Model and Examination of Interaction Terms

The fully adjusted model incorporated all of the significant variables from the univariate analysis (child test age, child gender, neighborhood, year house built, test year, and test season). This model then examined the association between each independent variable and geometric mean BLLs, while simultaneously controlling for the other independent variables that may affect the BLLs.

At this stage of model development, interaction terms were added to the model and examined. The addition of an interaction term to the model helps to determine whether the association between two variables (BLL and test year, for example) varies according to a third variable (neighborhood). Here, for instance, a significant interaction term would provide evidence that BLLs were declining faster over the years in one neighborhood compared to another.

Results of the fully adjusted model, with and without inclusion of interaction terms, are presented below.

5.3.2.1 Fully Adjusted Model without Interaction Terms

Table 23 summarizes the initial results of the fully adjusted model, which treated child test age data and test year data as continuous variables and all other independent variables as categorical. After adjusting for the other variables in the model, statistically significant results indicate the following trends:

- declining BLL with increasing test year;
- declining BLL with increasing child test age;

[16] For variables with only two categories, such as gender, the results of the F test are the same as the p values presented in the univariate results tables.

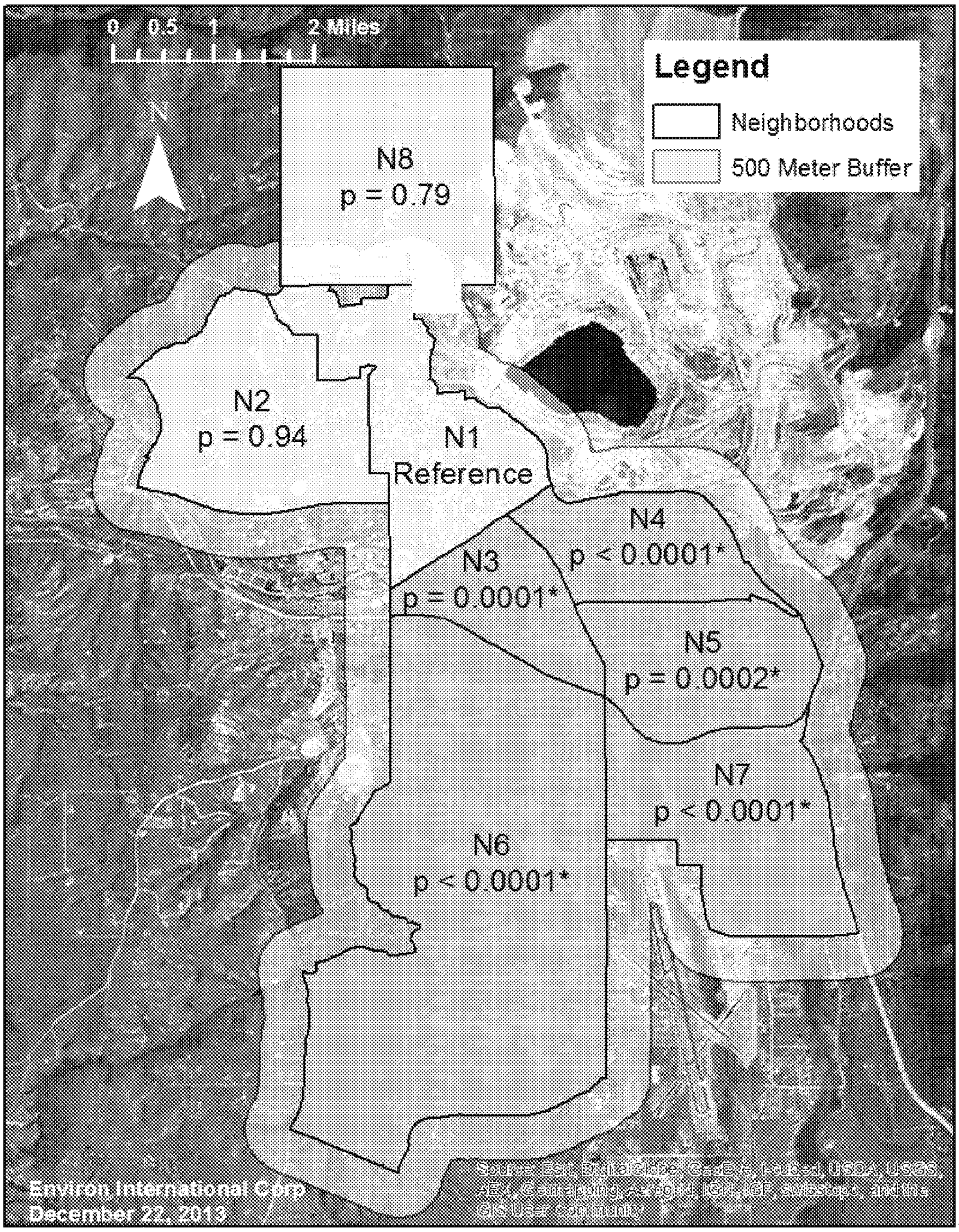
- lower BLLs in females than in males; and
- lower BLLs in winter/spring than summer/fall.

BLLs for children in all year house built groupings (1940-49, 1950-59, 1960-77, 1978 and later, and "missing") were lower than BLLs from participants in homes built prior to 1940 (the reference category for the house age variable). As discussed in section 3, older housing is associated with higher BLLs for a variety of reasons, thus the model results for BLLs based on different house age categories are as expected for any population.

Also in Table 23, the model compared Butte neighborhoods N2 through N8 to the reference neighborhood, N1. Geometric mean BLLs for N2 and N8 (2.74 µg/dL and 2.65 µg/dL, respectively) were not statistically different from N1 (2.70 µg/dL). All other neighborhoods (N3 through N7) had statistically lower BLLs than N1. The geometric mean BLLs for N3-N7 ranged from 1.83 µg/dL (N7) to 2.20 µg/dL (N4). These results are shown spatially in Figure 17.

Table 23: Results for Butte Neighborhood Comparison from Fully Adjusted Model				
Variable	**GM/Estimate (µg/dL)**	**95% LCL (µg/dL)**	**95% UCL (µg/dL)**	**p Value**
Child test age (estimate)	0.97	0.95	1.00	0.030*
Child gender				
Female	2.17	2.05	2.30	0.0004*
Male	2.42	2.28	2.56	Reference
Neighborhood				
N8	2.65	2.28	3.09	0.79
N7	1.85	1.59	2.16	<0.0001*
N6	2.04	1.90	2.19	<0.0001*
N5	2.15	1.93	2.38	0.0002*
N4	2.20	2.02	2.40	<0.0001*
N3	2.18	1.96	2.42	0.0001*
N2	2.72	2.50	2.97	0.94
N1	2.70	2.53	2.90	Reference
Year house built				
Missing	2.45	2.32	2.59	0.011*
Post 1977	1.90	1.63	2.21	<0.0001*
1960-1977	2.34	2.07	2.64	0.038*
1950-59	2.32	2.04	2.63	0.032*
1940-49	2.15	1.93	2.39	0.0001*
Pre1940	2.68	2.55	2.82	Reference
Test year (estimate)	0.88	0.87	0.89	<0.0001*
Test season				
Winter/Spring	2.08	1.97	2.20	<0.0001*
Summer/Fall	2.53	2.39	2.67	Reference

*Statistically significant ($p \leq 0.05$)
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit less.



*represents statistically significant p value; p values based on fully adjusted model (Table 23)

Figure 17: Comparison of Geometric Mean BLLs for Neighborhoods N2 through N7 with N1 as Reference

Pairwise comparisons of all combinations of year house built categories were also conducted to assess differences between categories. Tukey's multiple comparisons tests were used to calculate p values for these pairwise comparisons (Table 24). Based on this analysis, BLLs for individuals tested while living in houses built from 1940 to 1949[17] and after 1977 are statistically lower than BLLs for individuals tested while living in houses built prior to 1940. Additionally, BLLs from individuals where year house built data were missing were statistically higher than BLLs for individuals tested while living in houses built after 1977.

Table 24: Pairwise Comparisons of Year House Built Categories from Butte Neighborhood Comparison

Year Built Category	GM for Category (µg/dL)	Comparison Category	GM for Comparison Category (µg/dL)	p Value	Conclusion
Missing	2.45	Post 1977	1.90	**0.017***	"Post 1977" BLLs < "Missing" category BLLs
		1960-1977	2.34	0.98	No significant difference
		1950-59	2.32	0.97	
		1940-49	2.15	0.22	
		Pre1940	2.68	0.11	
Post 1977	1.90	1960-1977	2.34	0.26	No significant difference
		1950-59	2.32	0.34	
		1940-49	2.15	0.76	
		Pre1940	2.68	**0.0004***	"Post 1977" BLLs < "Pre1940" BLLs
1960-1977	2.34	1950-59	2.32	1.0000	No significant difference
		1940-49	2.15	0.91	
		Pre-1940	2.68	0.30	
1950-59	2.32	1940-49	2.15	0.94	No significant difference
		Pre1940	2.68	0.26	
1940-49	2.15	Pre1940	2.68	**0.0013***	"1940-49" BLLs < "Pre 1940" BLLs

*Statistically significant ($p \leq 0.05$) comparison between year built categories
BLL – Blood lead level; GM – Geometric mean.

Tukey's method was also used to evaluate pairwise neighborhood comparisons (Table 25). These results confirmed that there are no statistically significant differences in BLLs for individuals tested while living in neighborhoods N1, N2, and N8. BLLs corresponding to neighborhoods N3 through N7 are also not statistically different from each other. As shown in Figure 18, neighborhoods N1, N2, and N8 are clustered together in the "Uptown" area of Butte. The Uptown area is most proximal to the higher elevation areas of Butte where past and current

[17] Note: 195 out of 244 blood lead tests (80 percent) for this year house built category correspond to a single housing complex. This housing complex is located in N1 and blood lead records from this complex represent 96 percent of the records in N1 for this year house built category.

mining activities are concentrated. Consistent with increased mining activities, documented mineralized zones occurring throughout the bedrock and at the surface are also more prevalent in the Uptown area (Weed et al. 1897). South of Uptown, "the Flats" area corresponds to neighborhoods N3 through N7. Elevations in the Flats are lower than in Uptown. Mineralized zones are also far less prevalent in the Flats consistent with decreased historical and active mining activities in the Flats, relative to Uptown.

Table 25: Pairwise Comparisons of Neighborhoods from Butte Neighborhood Comparison

Neighborhood	GM for Neighborhood (µg/dL)	Comparison Neighborhood	GM for Comparison Neighborhood (µg/dL)	p Value	Conclusion
N8	2.65	N7	1.85	**0.021***	N8 BLLs > N7 BLLs
		N6	2.04	**0.034***	N8 BLLs > N6 BLLs
		N5	2.15	0.30	No Difference
		N4	2.20	0.36	
		N3	2.18	0.34	
		N2	2.72	1.0	
		N1	2.70	1.0	
N7	1.85	N6	2.04	0.94	No Difference
		N5	2.15	0.77	
		N4	2.20	0.48	
		N3	2.18	0.65	
		N2	2.72	**0.0003***	N2 BLLs > N7 BLLs
		N1	2.70	**0.0002***	N1 BLLs > N7 BLLs
N6	2.04	N5	2.15	0.99	No Difference
		N4	2.20	0.83	
		N3	2.18	0.96	
		N2	2.72	**<0.0001***	N2 BLLs > N6 BLLs
		N1	2.70	**<0.0001***	N1 BLLs > N6 BLLs
N5	2.15	N4	2.20	1.0	No Difference
		N3	2.18	1.0	
		N2	2.72	**0.012***	N2 BLLs > N5 BLLs
		N1	2.70	**0.0045***	N1 BLLs > N5 BLLs
N4	2.20	N3	2.18	1.0	No Difference
		N2	2.72	**0.0057***	N2 BLLs > N4 BLLs
		N1	2.70	**0.0010***	N1 BLLs > N4 BLLs
N3	2.18	N2	2.72	**0.011***	N2 BLLs > N3 BLLs
		N1	2.70	**0.0037***	N1 BLLs > N3 BLLs
N2	2.72	N1	2.70	1.0	No Difference

*Statistically significant ($p \leq 0.05$) comparison between geometric mean BLLs at two neighborhoods
BLL – Blood lead level; GM – Geometric mean.

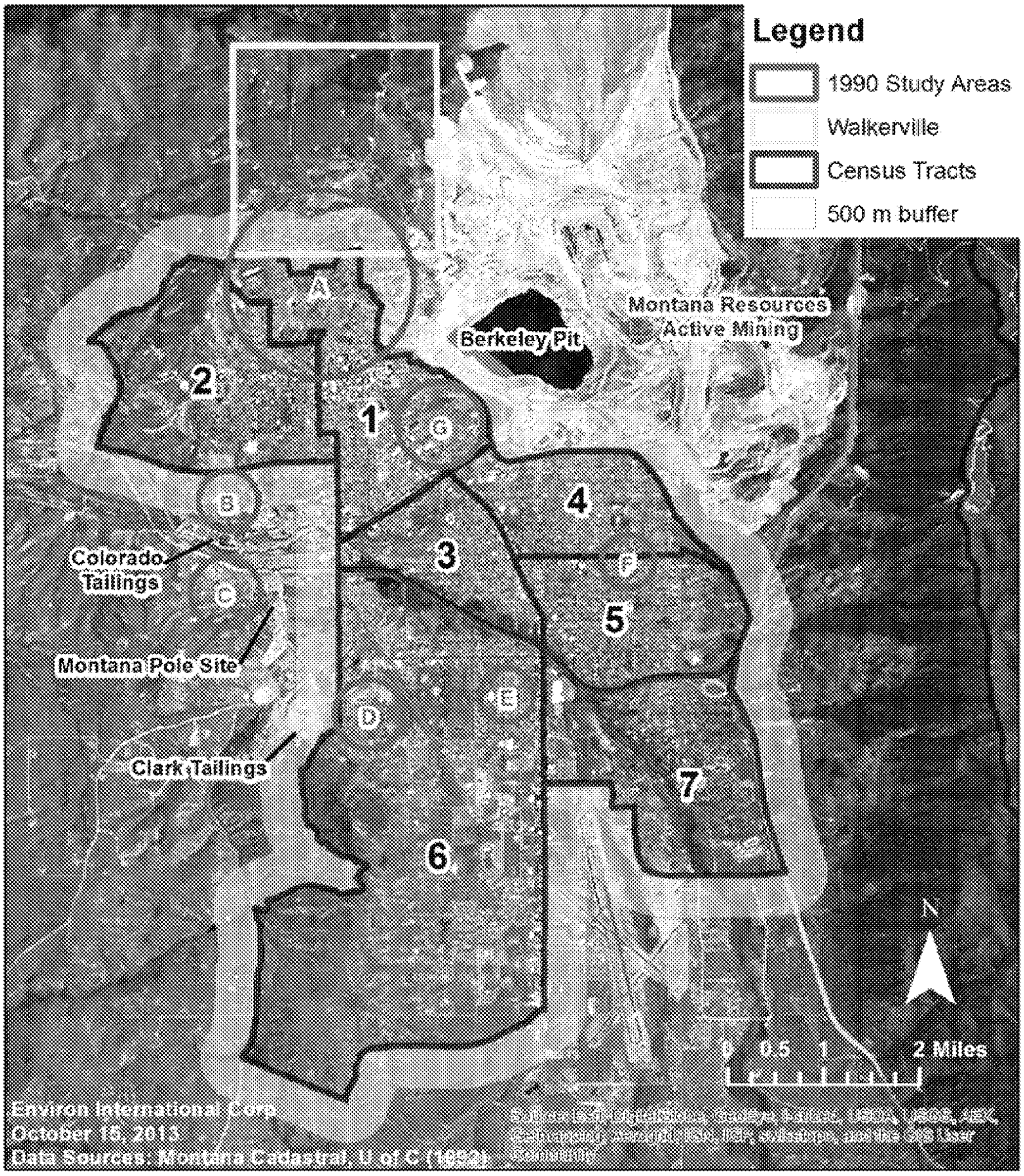


Figure 18: Map of Butte Showing Mining Areas

The fully adjusted model was run first with child test age as a continuous variable. However, as discussed in section 3, it has been consistently observed in the U.S. that young children between the ages of 1 and 3 years have the highest BLLs on average (Jones et al. 2009; CDC 2013b). Therefore, child test age was also set as a categorical variable comparing child test ages 12 to 35 months to child test ages 36 to 60 months. For this portion of the analysis, test year was also grouped into four categories (2003-04, 2005-06, 2007-08, 2009-10), and neighborhoods were grouped by area (i.e., Uptown and the Flats).

Consistent with results in Table 7, the results for this analysis showed the same significant effects (Table 26). The highest geometric mean BLL (3.54 µg/dL) corresponded to the 2003-04 test period, and geometric mean BLLs declined with each later test period. The geometric mean

BLL for children tested at ages 12 to 35 months was significantly higher than for children in the 36 to 60 month test age category (p=0.0002). The geometric mean BLL in Uptown was statistically higher than for the Flats (p<0.0001).

Table 26: Results from Fully Adjusted Model with All Variables as Categorical

Variable	GM (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p Value
Child test age (months)				
12-35	2.54	2.42	2.66	0.0002*
36-60	2.29	2.17	2.42	Reference
Child gender				
Female	2.28	2.16	2.41	0.0004*
Male	2.55	2.42	2.69	Reference
Neighborhood				
The Flats	2.14	2.04	2.25	<0.0001*
Uptown	2.72	2.57	2.88	Reference
Year house built				
Missing	2.54	2.42	2.67	0.0003*
Post 1977	1.96	1.68	2.27	<0.0001*
1960-1977	2.43	2.16	2.74	0.0092*
1950-59	2.48	2.20	2.80	0.026*
1940-49	2.28	2.07	2.51	<0.0001*
Pre1940	2.87	2.75	3.01	Reference
Test year				
2003-2004	3.54	3.31	3.78	<0.0001*
2005-2006	2.69	2.52	2.88	<0.0001*
2007-2008	2.24	2.10	2.39	<0.0001*
2009-2010	1.58	1.49	1.68	Reference
Test season				
Winter/Spring	2.18	2.07	2.29	<0.0001*
Summer/Fall	2.67	2.53	2.81	Reference

*Statistically significant compared to reference category (p ≤ 0.05)
GM – Geometric mean; LCL – Lower confidence limit; UCL – upper confidence limit.

5.3.2.2 Examine Interaction Terms

As noted earlier, interaction terms are added to a model to help determine whether the relationship between two variables (for instance, BLL and test year) vary according to a third variable (for instance, neighborhood). The interaction between neighborhood and test year was examined in the model to assess whether the effect of test year on BLLs differed between the individual neighborhoods (N1 through N8). For this interaction term, test year was treated as a continuous variable and the interaction term was found to be significant when added to the model (p <0.022). These results suggest an influence of test year on BLLs that varies by individual neighborhood.

A similar interaction was also examined using an interaction term based on continuous test year and neighborhood grouping (i.e., Uptown and the Flats); however, the addition of this interaction term to the model was not significant (p=0.15). [18]

5.3.3 Final Statistical Model (Stratified by Uptown vs. the Flats)

The final statistical model for the Butte neighborhood comparison was stratified by Uptown and the Flats to examine the influence of each of the remaining independent variables (child test age, child gender, year house built, test year, and test season) on BLL for Uptown vs. the Flats. Stratification of the model based on individual neighborhoods (N1 through N8) was initially conducted; however, sample sizes were too small for some variables on an individual neighborhood basis. Sample sizes for Uptown vs. the Flats do not fluctuate greatly over the four time periods evaluated in this study (Table 27).

Table 27: Sample Sizes for Uptown and The Flats by Two-Year Period

Years	Uptown	The Flats
2003-2004	295	356
2005-2006	253	369
2007-2008	300	356
2009-2010	354	441

To determine whether the rate of decline in BLLs over time is different in Uptown than the Flats, the coefficients and standard errors for test year (treated as a continuous variable) from the adjusted model were used to calculate a Chi-squared test statistic. This test statistic with one degree of freedom was then compared to the Chi Square distribution to determine if the null hypothesis that the coefficients were the same could be rejected at a significance levels of α = 0.05. Results of these analyses are summarized below.

5.4 Butte Neighborhood Comparison Model Results

Table 28 summarizes the results of the final stratified model for the Butte neighborhood comparison. For each neighborhood area or "source" considered in the stratified model, geometric mean BLLs and confidence intervals are presented. The influence of each independent variable (i.e., child test age, child gender, test year, house age, or test season) on BLL is calculated by the model while accounting for the influences of all the other variables. Confidence intervals may be compared across each variable category for Uptown and the Flats to provide an indication of whether BLLs for each area are statistically different. Statistical comparisons of results for Uptown and the Flats were also performed using a t-test with p values comparing the neighborhood groups (Table 28).

[18] Interaction terms were also considered for year house built and neighborhood, as well as test year as a categorical variable and neighborhood group. Both treatments lacked sufficient statistical power for the significance of the term to be estimated.

Table 28: Results from Stratified Model with P Values Comparing Uptown to the Flats									
	Uptown				the Flats				Comparison**
Variable	GM (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p Value	GM (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p Value	p Value
Child test age (months)									
12-35	2.67	2.43	2.94	0.087	2.34	2.19	2.49	0.0033*	0.026*
36-60	2.48	2.25	2.75	Reference	2.11	1.97	2.26	Reference	0.012*
Child gender									
Female	2.42	2.18	2.68	0.0073*	2.13	1.98	2.28	0.031*	0.044*
Male	2.74	2.49	3.02	Reference	2.32	2.16	2.48	Reference	0.0086*
Year house built									
Missing	3.16	2.9	3.43	0.87	2.15	2.02	2.29	<0.0001*	<0.0001*
Post 1977	1.69	1.19	2.39	0.0006*	1.85	1.57	2.19	0.0002*	0.49
1960-1977	2.55	1.91	3.41	0.14	2.18	1.91	2.48	0.012*	0.32
1950-59	2.73	2.14	3.48	0.22	2.18	1.9	2.51	0.020*	0.086
1940-49	2.48	2.22	2.77	0.0002*	2.42	1.96	2.99	0.47	0.92
Pre1940	3.18	2.98	3.4	Reference	2.62	2.46	2.79	Reference	<0.0001*
Test year									
2003-2004	3.55	3.15	3.99	<0.0001*	3.42	3.14	3.73	<0.0001*	0.61
2005-2006	2.83	2.51	3.19	<0.0001*	2.5	2.3	2.72	<0.0001*	0.085
2007-2008	2.56	2.29	2.87	<0.0001*	1.98	1.81	2.15	<0.0001*	0.0007*
2009-2010	1.71	1.53	1.91	Reference	1.44	1.33	1.55	Reference	0.018*
Test season									
Winter/Spring	2.29	2.07	2.52	<0.0001*	2.05	1.92	2.19	<0.0001*	0.086
Summer/Fall	2.9	2.63	3.2	Reference	2.41	2.25	2.57	Reference	0.0023*

*Statistically significant ($p \leq 0.05$)
** p value comparing GM in Uptown to the GM in the Flats
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit.

After adjustment for other variables in the model, BLL trends are generally similar for Uptown and the Flats. General trends common to both neighborhood groups include the following:

- BLLs are lower in the later study periods (Figure 19). In Uptown, BLLs decline from a mean of 3.55 µg/dL in 2003-2004 to a mean of 1.71 µg/dL in 2009-2010. In the Flats there is a decline as well, from 3.42 µg/dL in 2003-2004 to 1.44 µg/dL in 2009-2010.

- BLLs are lower for children aged 36 to 60 months at the time of test than for children aged 12 to 35 months.
- BLLs are lower for females than for males.
- BLLs are lower for children tested in the winter/spring than in the summer/fall season.

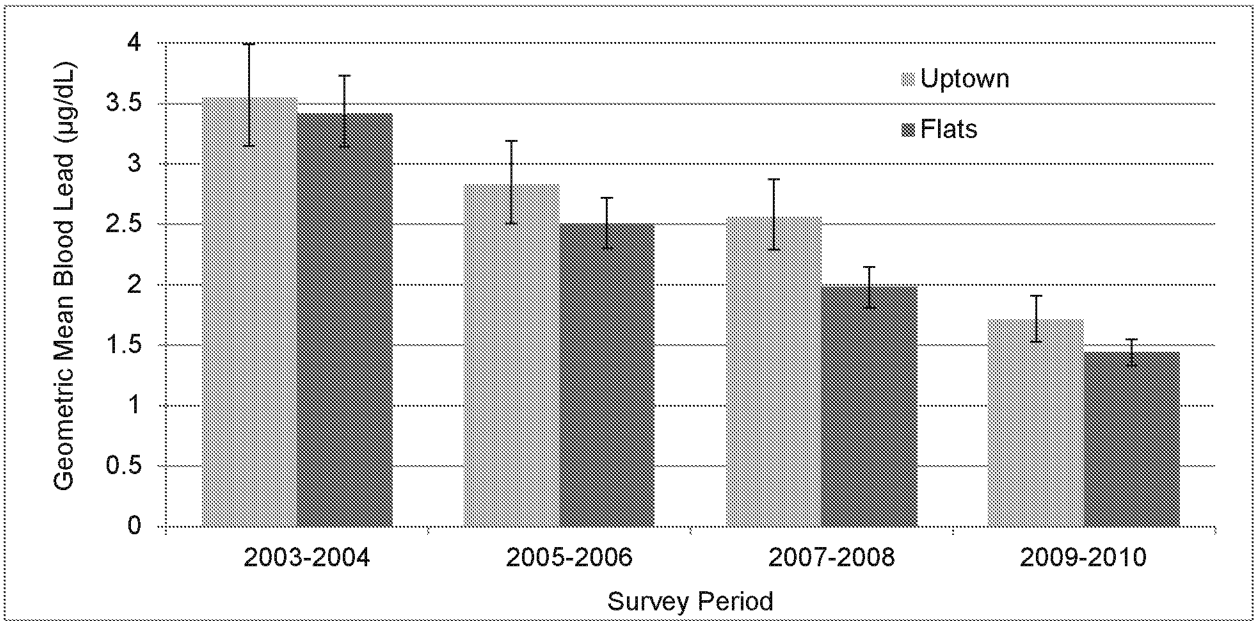


Figure 19: Modeled Geometric Mean Blood Lead Levels for Uptown vs. the Flats by Test Year with 95% Confidence Intervals

In both the Flats and Uptown, BLLs tend to increase as house age increases. In the Flats, children living homes built prior to 1940 have mean BLLs that are significantly higher than those of children living in homes built in 1950 or later. In Uptown, BLLs from children living in pre-1940 homes are significantly higher than those of children living in homes built from 1940 to 1949 or from 1978 and later.

Comparing across neighborhood groups, geometric means in Uptown tend to be higher than geometric means in the Flats. Specifically, BLLs in Uptown are significantly higher than in the Flats for:

- the two most recent test periods of 2007-2008 and 2009-2010;
- children tested in the summer/fall;
- children of both age categories and genders; and
- children living in homes built prior to 1940 or in homes of unknown ages (i.e., the missing category).

Controlling for the influence of all other variables, BLLs for children living in houses built after 1939 were not statistically different between Uptown and the Flats. BLLs for Uptown and the

Flats were also not statistically different for the earliest two test periods and the winter/spring test season.

Based on the results of the Chi-squared test, the rate of BLL decline from 2003 through 2010 is not statistically different (p=0.069) for Uptown and the Flats. In Uptown, BLLs have declined at a rate of 11 percent per two-year period compared to a decline of 14 percent in the Flats.

5.5 Summary and Conclusions

Statistical models were built to compare BLLs across Butte neighborhoods while accounting for other independent variables that can influence BLLs. Child test age, child gender, year house built, child neighborhood, test year, and test season were included in the models after determining the significance of each variable in the univariate analysis. Results of a fully adjusted model were examined along with the model stratified by neighborhood area, Uptown and the Flats. In both the fully adjusted model and the stratified model, statistically significant results indicate the follow trends:

- BLLs declined over time during the study periods examined.
- BLLs for children aged 36 to 60 months at the time of test were lower than for children aged 12 to 35 months.
- BLLs in females were lower than in males.
- BLLs for children tested in the winter/spring were lower than in the summer/fall season.

Overall, the final stratified model suggests BLLs in Uptown are higher than in the Flats when accounting for the influence of other variables, and these differences are frequently statistically significant. There is also a consistent trend with regard to declining BLLs over time for both areas of Butte, and, despite the higher BLLs in Uptown, the rate of decline is not statistically different between the two areas.

Uptown BLLs were significantly higher than BLLs for the Flats during the summer/fall test season when the greatest exposures to outdoor sources are expected, but BLLs were not different between these areas during the winter/spring test season when outdoor exposures are more limited. This suggests that outdoor sources of lead exposures may contribute more to BLLs for residents of Uptown than for the Flats. In this study, the model does not include variables for specific sources of lead exposure within the indoor and outdoor environment that are present in Butte, therefore, it is not possible to identify which outdoor source or sources might be responsible for the higher BLLs in Uptown during warmer months. We do know that Uptown is spatially located in closer proximity to areas in Butte where past and ongoing mining activities have been concentrated. We also know that naturally-occurring mineralized zones are more prevalent in these areas and that most of the oldest homes in Butte, which are most likely to have lead paint, are located in Uptown. Each of these conditions could contribute to the seasonal BLL difference identified between Uptown and the Flats.

To assess whether the decline in BLLs for both Uptown and the Flats continued beyond 2010, available Butte blood lead records collected in 2011 were added to the model, and blood lead data for each two-year study period were compared to the 2011 test year. For both the Flats and Uptown, 2011 data were not statistically different from data for 2009-2010 (see Appendix F for complete summary of the model results with 2011 data added), while each of the three earliest test periods is statistically different from 2011. Comparison of 2011 data for Uptown and the Flats using a t-test supports the earlier finding that BLLs in Uptown are statistically higher (Appendix F).

During the study period, the CDC recommended 10.0 µg/dL as a blood lead "level of concern" when based on a confirmed venous blood draw. This level of concern was used as a risk management tool by the BSB Health Department to identify children who might have elevated lead exposures so that actions to reduce such exposures could be initiated. Children with confirmed venous blood lead results exceeding 9.9 µg/dL were referred for case management, including home visits when appropriate, intensive education for the family, environmental investigation and follow up blood lead testing. According to BSB Health Department's annual reports of clinical and educational interventions, screening blood lead results confirmed to exceed 9.9 µg/dL declined from 1.4 percent in 2003-2004 to 0.1 percent in 2010. The Health Department identified a variety of suspected causes of elevated blood lead levels in these children. Starting in 2013, home visits were scheduled for all children with blood lead levels of 5.0 µg/dL or higher, consistent with a new blood lead reference level issued by the CDC.

Analysis of the percentages of Butte children with BLLs above the CDC level of concern during the study period (10 µg/dL) and in comparison to the current reference level (5 µg/dL) was not included in the neighborhood comparison statistical model, but was evaluated outside of the model. The same Butte blood lead data used in the model were used for the analysis of percentages; however, to address repeat measures, only the first measurement for each individual within the full study time period was included. This approach differs from how repeat measures were accounted for in the statistical model and was necessary because including repeat measures in the percentage of results that exceed 5.0 or 10.0 µg/dL would limit how well those percentages could be compared to values for other datasets.[19] Figure 20 shows the percentage of Butte blood lead results greater than the current CDC reference value for five time periods from 2003 to early December 2011. Figure 21 has the equivalent results for the percentages of BLLs greater than or equal to the prior CDC level of concern (10.0 µg/dL).

[19] In particular, since exposure reduction follow up in Butte was initiated during the 2003-2010 study period only when a confirmed blood lead result exceeded CDC's former level of concern, 10.0 µg/dL, children tested with results between 5.0 and 10.0 µg/dL, who were not referred for follow up, but may have continued to be retested periodically and would, therefore, contribute to an increase in the percentages above 5.0 µg/dL. Similarly, Butte children tested multiple times with results below 5.0 µg/dL would contribute to a decrease in the percentages that would also limit the value of comparisons to other data (i.e., national data).

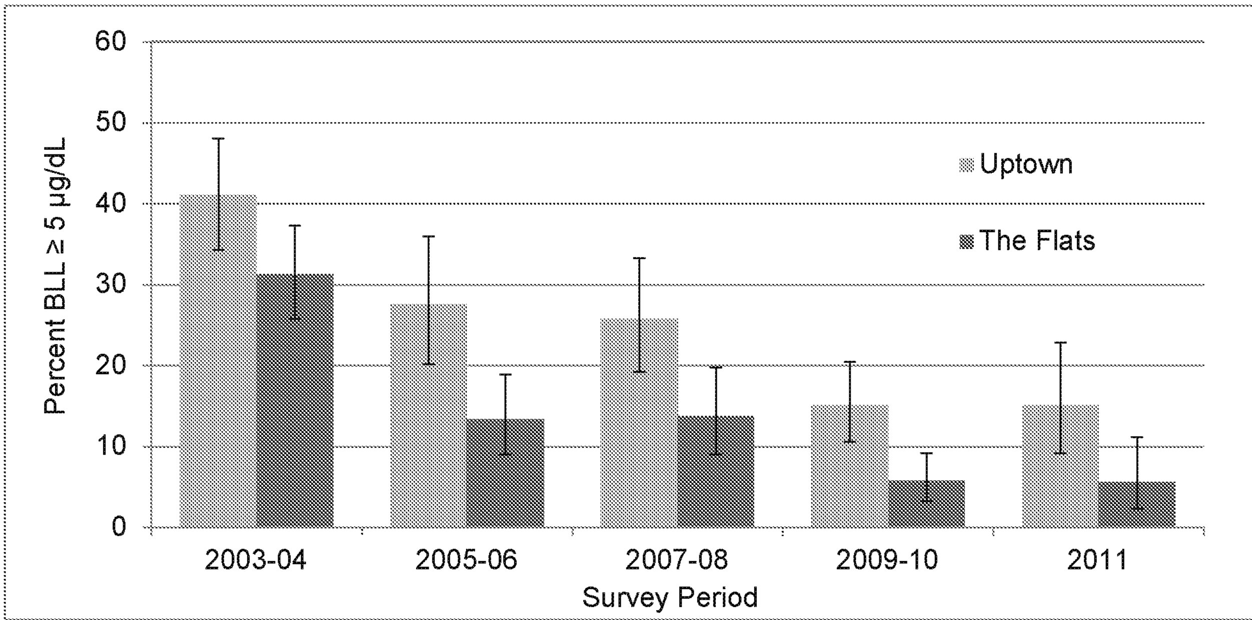


Figure 20: Percentage of Blood Lead Levels ≥ 5.0 µg/dL over Time for Uptown vs. the Flats with 95% Confidence Intervals

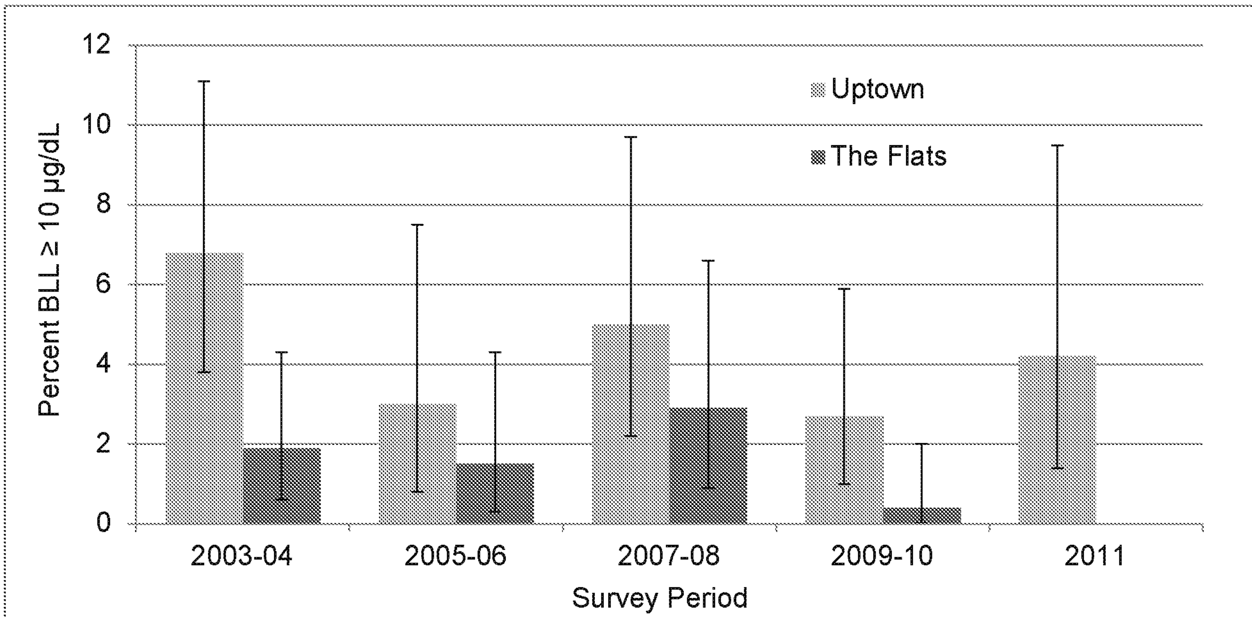


Figure 21: Percentage of Blood Lead Levels ≥ 10.0 µg/dL over Time for Uptown vs. the Flats with 95% Confidence Intervals

Consistent with the model analysis, these data suggest that higher overall BLLs in Uptown continue to be evident even with the significant decline in BLLs over time. For both Uptown and the Flats, there has been a dramatic decline in the percent of children tested with BLLs greater than 5.0 µg/dL from the earliest study test period (2003-2004) to the most recent test period (2009-2010) (Figure 20). The percent of children in Uptown with BLLs greater than 5.0 µg/dL declined from 40.6 to 15.1 percent for the 2003-2004 to 2009-2010 test periods, respectively. In the Flats, the percent greater than 5.0 µg/dL declined from 31.0 to 5.1 percent, respectively. In both areas, the percentages that exceed the CDC reference value did not decline further from the 2009-2010 test period compared to 2011.

Because BLLs greater than 10.0 µg/dL are less common, the percentages of the records above this level have fluctuated over the survey periods (Figure 21). In Uptown, the percentage has decreased from 6.8 percent to 4.2 percent above 10.0 µg/dL from 2003-2011. In the Flats, a smaller percentage of records were above 10.0 µg/dL. In the earliest survey period (2003-2004), 1.9 percent of records were above this level, and in 2011 there were no records elevated to 10.0 µg/dL. Additionally, from the most recent study period of 2009-2010, the distribution of BLLs in Uptown and the Flats is shown in Figure 22, with lines marking the values above 5.0 and 10.0 µg/dL.

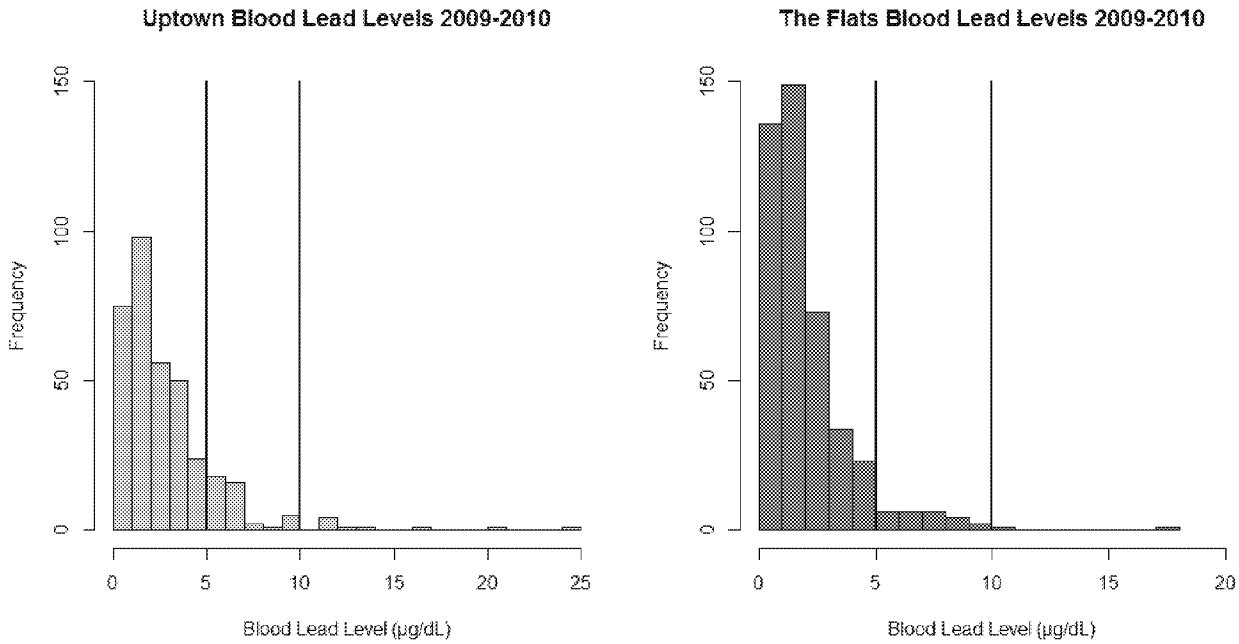


Figure 22: Blood Lead Frequency Distributions for Uptown and the Flats for 2009-2010

As with the current study, BLL differences across different areas of Butte were also identified in the 1990 Butte exposure study (summarized in section 5.1). There are considerable differences between the study design for the 1990 study vs. the current study (e.g., study purpose, geographic areas sampled, distribution of samples over all Butte neighborhoods, recruitment of the target populations, etc.), which limit direct comparison of study results. In addition, only summary data are available for the 1990 study, which prevents robust statistical comparisons of these data to the current study. Nonetheless, some additional information may be gained by looking at the magnitude of BLL differences across Butte neighborhoods in 1990 in comparison to the most recent test period (2009-2010) in the current study. While the 1990 study did not group neighborhood data by Uptown or the Flats as in this study, these areas are approximated by Areas A and G and Areas E and F, respectively, from the 1990 study. Table 18 provides summary statistics for these areas from the 1990 study, which can be used to calculate the percent difference in BLLs for the combined Areas AG vs. combined Areas EF. Geometric means for each area combined were weighted to account for significant differences in sample sizes. Area AG had a geometric mean BLL 30 percent higher than Area EF based on samples collected during August and September 1990. This compares to 38 percent higher geometric mean BLLs in Uptown vs. the Flats based on data collected during the 2009-2010 summer/fall season. Recognizing the limits to this analysis described previously, these values confirm that despite the dramatic decrease in BLLs in Butte, the difference between Uptown and the Flats persists.

6 Consideration of Supplemental Information

As described in the preceding sections, statistical analyses supporting the Butte neighborhood comparison and the Butte comparison to NHANES focused on blood lead data for Butte and NHANES without consideration of other kinds of exposure information, such as available environmental data. Similarly, comparison of the Butte data to a reference population focused on NHANES following approval of this dataset for use in the primary study analyses. However, interpretation of the primary study analyses was supplemented by consideration of environmental data from the RMAP and of available blood lead data identified during the process of selecting NHANES as the blood lead reference dataset for this study.

6.1 Consideration of RMAP Environmental Data

BSB maintains a database of residential metals sampling and abatement information as part of the RMAP. While the RMAP environmental database contains thousands of records documenting extensive assessment and abatement activities conducted within the study area, a relatively small subset of all study area properties include both blood lead and abatement records, which limited analysis of the two datasets to a neighborhood basis, rather than property-specific basis. Details about the RMAP database and its consideration in this study are summarized below.

BSB provided this database to ENVIRON in June of 2013. The RMAP database includes details of sampling for indoor dust, outdoor soil and paint, as well as indoor and outdoor abatements that have taken place between February 1992 and May 2013 throughout the RMAP area. BSB also publishes "Annual Construction Completion" reports that summarize RMAP activities conducted each year and/or planned for subsequent years. As of 2013, the program has sampled approximately 2,340 of 3,646 properties (64 percent).

The database includes records for 7,340 soil/dust samples (from 1,850 unique parcels), 899 paint samples (from 812 unique parcels) and 711 abatements (from 519 unique parcels). A total of 168 Butte blood lead records from the refined child dataset evaluated in this study correspond to properties that were abated through all years of the RMAP (based on matching address). These include abatements of interior dust and/or paint (including basements and attic dust) and exterior paint and/or yard soil. Of these blood lead records, 126 occurred after abatement took place at the property, 34 took place before abatement occurred, and 8 occurred at some time during the abatement process (i.e., in cases where multiple abatements had occurred at a single property). However, where a single property is associated with both blood lead data and RMAP data, the two types of information may or may not be related to each other. This is because blood lead records that were collected in conjunction with RMAP activities were not documented as such. Similarly, individuals who participated in blood lead testing at WIC and were encouraged to participate in the RMAP were also not tracked. Additionally, pre- and post-abatement blood lead testing is not tracked as such in the records provided by BSB.

Consideration of the environmental data contained in the RMAP was accomplished by linking each RMAP property to one of the eight study neighborhoods in Butte (N1 through N8; see Appendix C for details). While only a small number of blood lead records match the RMAP records on a property-specific level, RMAP summary statistics are based on all records available for a given neighborhood. Counts of RMAP activities for each neighborhood area (Uptown and the Flats) were then compared to provide an indicator of the intensity of exposure reduction activities conducted within each area of Butte over a specific timeframe. As shown in Figures 23 and 24, the vast majority of the RMAP activities occurred in the Uptown neighborhoods (N1, N2, N8), which are geographically closer to historic mining and ongoing mining associated with Montana Resources operations (Figure 19). Naturally-occurring mineralization is also more prevalent in Uptown than in the Flats, as well as an increased prevalence of older housing.

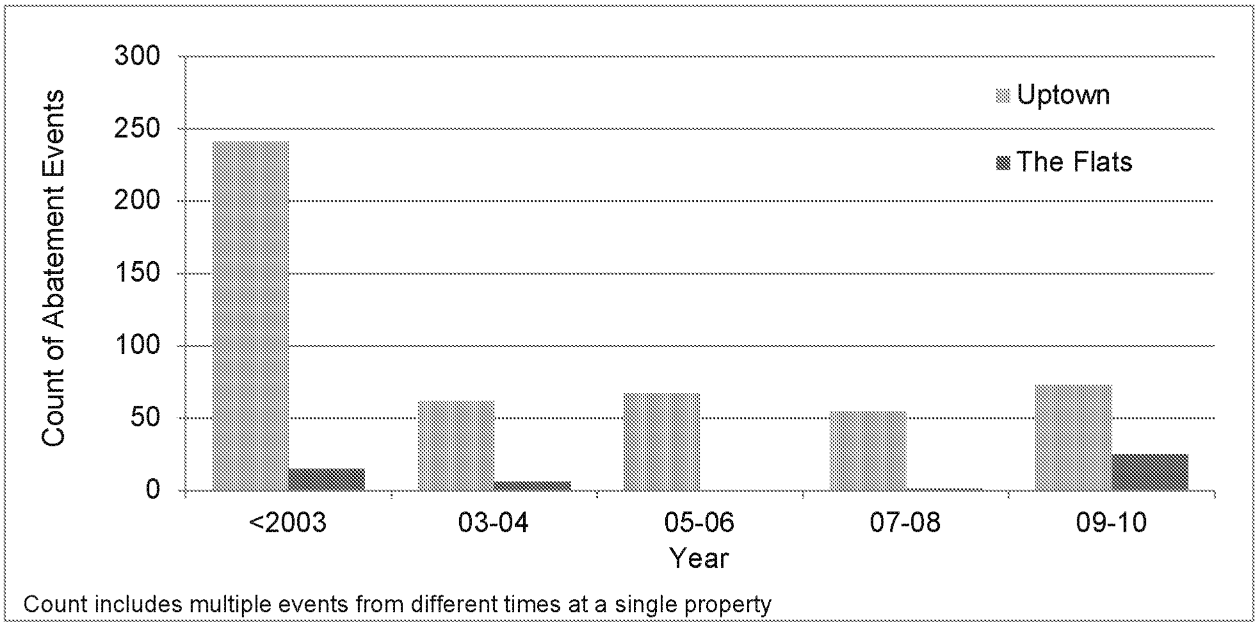


Figure 23: Count of All RMAP Abatement Events (Soil, Dust, Paint) over Time for Uptown vs. the Flats~~Count of RMAP Soil/Dust Sampling Events over Time for Uptown vs. the Flats~~

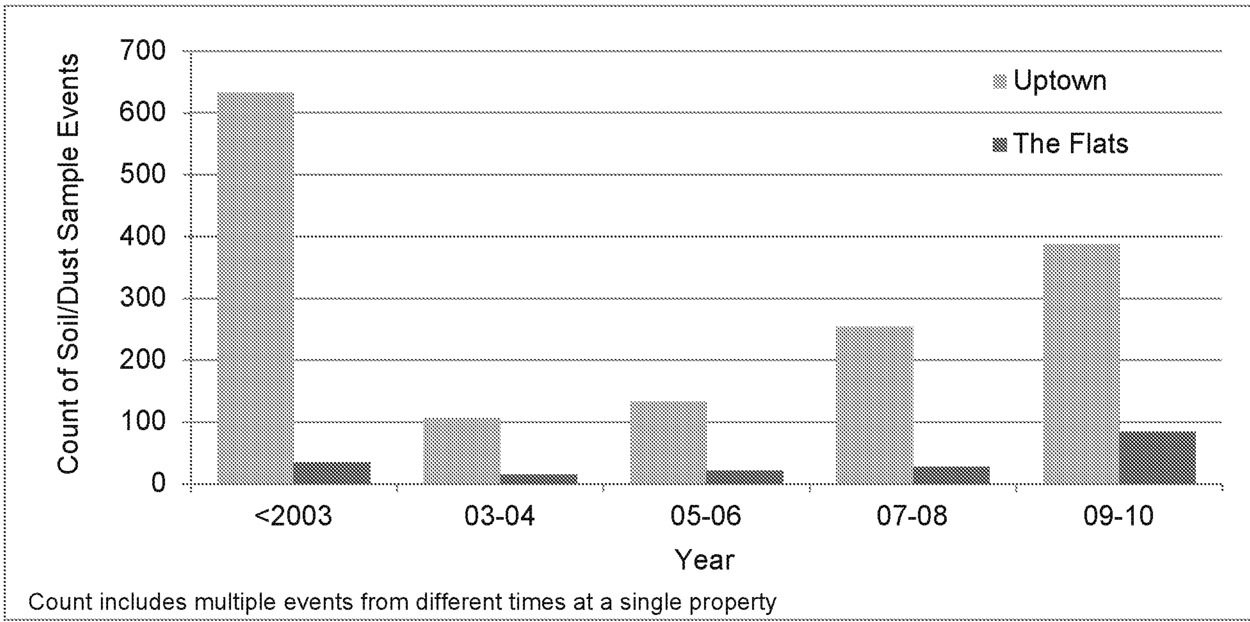


Figure 24: Count of RMAP Soil/Dust Sampling Events over Time for Uptown vs. the Flats ~~Count of All RMAP Abatement Events (Soil, Dust, Paint) over Time for Uptown vs. the Flats~~

A trend toward increased sampling over time is evident for both areas. For Uptown, a total of 881 sampling events occurred from 2003 to 2010 versus 633 sampling events prior to 2003. A proportionally greater increase in sampling events occurred in the Flats, from pre-2003 (35 events) to 2003 through 2010 (147 events). The increased intensity of RMAP activities in neighborhoods further from Uptown likely reflects early prioritization of RMAP outreach toward residents of Uptown where more of the oldest homes in Butte are located and in closer proximity to mining-related exposure sources.

Prioritization of properties addressed by RMAP is detailed in section 5.0 of the final RMAP (BSB/AR 2010), which states:

> “Residential properties shall be remediated if sampling data indicate that action levels for yard soil or interior living space dust are exceeded or for indoor air when mercury concentrations exceed the mercury vapor action level.”

and,

> “The Program utilizes a prioritized approach which addresses affected and sensitive populations as a priority; however, BSB will attempt to access every property within the BPSOU and Adjacent Area, and shall carry out abatement where required by the assessment results.”

The data represented in Figures 23 and 24 reflect higher numbers of abatements relative to sampling events for both Uptown and the Flats prior to 2003 (38 and 43 percent, respectively) than during the study period (29 and 22 percent, respectively). As the program prioritized properties that had the highest potential for exposures and most sensitive populations, finding a higher rate of abatements prior to 2003 is not unexpected. It is notable, however, that despite a much greater sampling intensity in Uptown than in the Flats prior to 2003 and the increased rate of sampling in the Flats relative to Uptown since then, there is little difference between Uptown and the Flats in terms of the proportion of abatements to sampling events within each time period. This suggests that while lead exposure potential has been characterized at more properties within Uptown than the Flats, the frequency of results that trigger abatements in both areas is similar. Looking at these abatements more carefully, Figures 25 and 26 show the numbers of yard soil abatements and paint abatements over time for both areas. Based on these data, the proportion of paint to yard abatements is higher in the Flats than in Uptown where the ratio is closer to one. The results of the Butte neighborhood comparison model suggested that outdoor lead exposures in Uptown, including from older houses, might contribute to the higher BLLs for Uptown relative to the Flats. These RMAP abatement data further support the potential that both soil and paint are contributing to higher lead exposures in Uptown, while in the Flats, the relative contribution of soil to overall exposures appears to be lower.

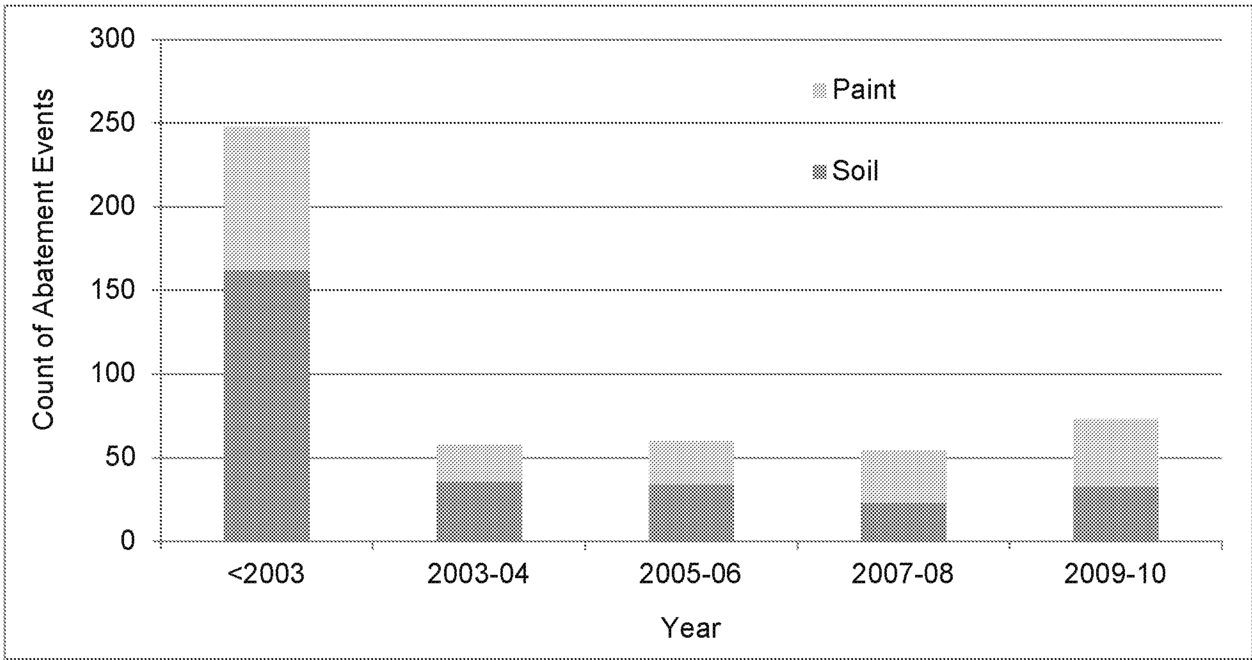


Figure 25: Abatement Events in Uptown by Type

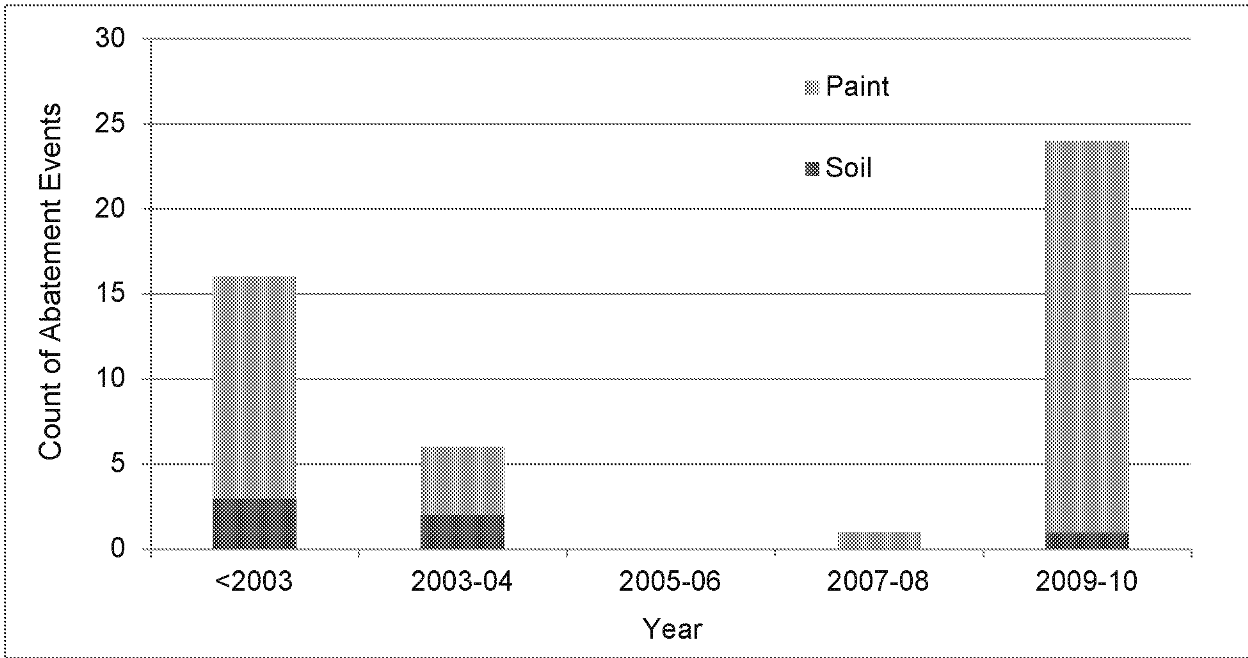


Figure 26: Abatement Events in the Flats by Type

6.2 Consideration of Community-Based Blood Lead Data

In addition to NHANES, several other community-based blood lead data sources were researched and evaluated prior to selecting NHANES for use in the health study. As described in the reference data technical memorandum (ENVIRON 2013b; Appendix D), the reference blood lead data source proposed for use in the study was intended to support assessment of whether or not the distribution of BLLs in the Butte community and in a reference population are similar over the same period evaluated. As discussed in section 4 and in the approved reference data technical memorandum, examination of the comparability of factors that may influence BLLs across datasets is an important consideration for selection of a reference blood lead data source. Such factors include demographic characteristics (e.g., gender, age, income level, etc.), age of housing stock within the community, blood lead testing and analytical methodologies, as well as whether or not a potential reference dataset has a Superfund site history similar to Butte.

The search for blood lead data from potentially comparable communities was a challenging exercise in that blood lead data were often limited or not available for communities with characteristics most closely aligned with those of Butte. Ultimately, only the NHANES data source was deemed suitable for use in the study to address the primary study objectives. However, as stated in the reference data technical memorandum: "Additional comparative analyses using subsets of some of the other reference data sources identified may also be useful for interpreting the distribution of BLLs in Butte and these will be considered further as development of proposed statistical approaches for use in the Butte health study proceeds." Accordingly, available raw community data obtained during the conduct of this study were re-evaluated to determine whether any could be meaningfully compared to the distribution of BLLs in Butte. Summary data (geometric means without associated confidence intervals) were available from Lake County, Colorado for 2006-2010 and from Bunker Hill, Idaho for 2007-2009, and though these were considered, the lack of information about data treatments and test population characteristics associated with these summary data limit how useful they are for interpreting the distribution of BLLs in Butte.

De-identified raw blood lead data were available only for two other datasets overlapping with the Butte study data test years and child ages. One dataset was provided by the Head Start program in Kalispell, Montana and is limited to the 2010 test year. The Kalispell data are limited to 151 children who reside in Flathead County. As with Butte, these data are from capillary sampling with a detection limit of 1.0 µg/dL. It is unknown whether any of these data represent repeat measurements for the same child. Individual results only include date of sample collection and analytical result, and do not include the age (although the likely range is 36 to 60 months) or gender of the child. Unlike Butte, Kalispell is not associated with a Superfund site and Kalispell has no known major industrial point-sources of lead. Newer housing stock in Kalispell is not comparable to distribution of home ages in Butte-Silver Bow County, with 20 percent built before 1950 in Kalispell vs. 48 percent in Butte. However, poverty levels in the tested population for the Kalispell data are likely to be higher than for the Butte dataset. This is because the income qualification for WIC in Butte is a family income equal to or less than 175 percent of the poverty level; whereas the income qualification for Head Start in Kalispell is 100 percent of the poverty level. Given these differences/uncertainties and the important influence of both poverty and house age on BLLs, it was determined that statistical comparison of the Kalispell and Butte datasets would not be useful for interpreting the distribution of BLLs in Butte.

The other raw dataset was provided by the East Helena Superfund Lead Education and Abatement Program (LEAP) and is limited to a single month, September, of the 2008 test year. The East Helena dataset is comprised of blood lead results for approximately 80 children tested at ages 1 through 5 years who resided in Lewis and Clark County. Repeat measurements are included for some children, test date is missing in a few cases, and month age or dates of birth are not included, so it is possible that some of the children tested at the age of 5 years would be outside of our study age range. This population of children lives within the area of influence of a former lead smelter and had other demographic differences from the Butte population as detailed in the reference data technical memorandum (ENVIRON 2013b). The detection limits for these data are 0.5 and 2.0 µg/dL; however, the records considered not-detected are not distinguished in the dataset. Given the availability of only a single month of data for comparison, as well as other uncertainties associated with the East Helena dataset and comparability of the tested population to the Butte study population, it was determined that statistical comparison of the Kalispell and Butte datasets would not be useful for interpreting the distribution of BLLs in Butte.

7 Conclusions and Recommendations

As described in section 1.3, the principal question to be addressed by this study is:

> Do environmental and biomonitoring data collected for the RMAP support a finding that the program has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community and, if not, what actions can be taken to improve the efficacy of the RMAP?

To address this question, this study focused on characterizing the distribution of Butte BLLs in comparison to a selected reference population (NHANES) and across Butte. With consideration of nearly 3,000 blood lead records collected from Butte children from 2003 through 2010, the primary and supplemental analyses detailed in this report were conducted to support two lines of evidence. First, whether or not the distributions of BLLs in the Butte community and in a reference population are similar over the same period evaluated. Second, whether or not statistically significant differences in BLLs across neighborhoods within the Butte community, measured in conjunction with the RMAP, are reduced relative to differences documented pre-RMAP in BLLs across Butte neighborhoods. As detailed in the approved study work plan, evaluation of these two lines of evidence may yield one of four possible outcomes related to the following hypotheses pairs:

The null and alternative hypotheses for first line of evidence (H1) are:

$H1_0$: BLL distributions within the study population are significantly higher than BLL distributions for the comparison population based on statistical comparisons of data collected over the same time period.

$H1_A$: BLL distributions within the study population are not significantly higher than BLL distributions for the comparison population based on statistical comparisons of data collected over the same time period.

The null and alternative hypotheses for the second line of evidence (H2) are:

$H2_0$: Statistically significant differences in BLLs between specific neighborhoods evaluated in 1990 are still evident based on more recent BLL data.

$H2_A$: Statistically significant differences in BLLs between specific neighborhoods evaluated in 1990 are no longer evident based on more recent BLL data. Unless the data analysis provides conclusive information to reject the null hypotheses for the alternative hypotheses, we assume that the null hypotheses are true.

Based on the Butte vs. NHANES comparisons described in section 4, the distribution of BLLs for Butte children are significantly higher than corresponding BLLs for the reference population (NHANES) for three of the four time periods evaluated in this study. However, for the most recent time period evaluated, 2009-2010, statistically significant differences between Butte and NHANES BLLs did not persist. Thus, this study does not provide conclusive information to reject the null hypothesis, $H1_0$, for all time periods considered except the most recent time period.

The lack of a significant difference between Butte and the NHANES reference dataset during the 2009-2010 reflects a greater rate of decline in Butte blood lead levels during the prior time periods. The specific factors causing the higher rate of decline in Butte cannot be determined based on this analysis, but such factors could include ongoing RMAP response efforts, as well as reductions in other lead exposure sources or risk factors.

Further, supplemental consideration of the frequency of blood lead results for the adjusted NHANES data for 2005-2008, the timeframe that corresponds to the NHANES data underlying the CDC blood lead reference value, suggests the potential significance of older housing and increased poverty levels in Butte on higher BLLs and supports the importance of matching blood lead risk factors such as house age, poverty, and race when seeking to explain BLL differences between two populations.

Based on the Butte neighborhood analyses described in section 5, statistically significant differences in BLLs across different Butte neighborhoods are evident over the study period evaluated. During all four study periods (i.e., 2003-2004, 2005-2006, 2007-2008, and 2009-2010) children living in neighborhoods in Uptown were found to have higher average blood lead levels than children living in the Flats. The magnitude of the neighborhood differences was similar to the difference observed in the 1990 study. Thus, this study does not provide conclusive information to reject the null hypothesis, $H2_0$.

Although the results of this study suggest a marked trend in declining BLLs in Butte over four consecutive two-year periods from 2003 through 2010, as with the 1990 lead exposure study conducted in Butte, geometric mean BLLs in Uptown were consistently higher than corresponding BLLs in the Flats and the differences were statistically significant across almost all variable categories considered in the final stratified model. The difference between Uptown and the Flats was greater during the summer when outdoor exposures would be greatest. This suggests that for Uptown children, outdoor sources of lead exposures may be more important than for children living in the Flats. Increased prevalence of older housing and mineralized zones in Uptown, as well as closer proximity to past and ongoing mining areas may all contribute to increased outdoor exposures to lead in Uptown relative to the Flats. Supplemental evaluation of the RMAP abatement data further supports the potential that both soil and paint are contributing to higher lead exposures in Uptown, while in the Flats, the relative contribution of soil to overall exposures appears to be lower. Despite the higher BLLs in Uptown vs. the Flats, the rate of decline in BLLs across all of Butte has been considerable over time and is not statistically different between Uptown and the Flats.

Given that Butte BLLs for the most recent time period evaluated are no longer statistically different from the reference population, but differences were identified in earlier years, we conclude that the RMAP has been effective and should be continued. Coupled with other extensive source remediation activities in Butte, the RMAP has been an important community-wide mechanism for identifying and reducing lead exposures. Based on the findings of this study, we recommend BSB consider the following to assure the RMAP's continued effectiveness in identifying and reducing lead exposures in the Butte Priority Soils Operable Unit:

1. Continue to follow the CDC recommendations for confirming screening blood lead test results by venous sampling if greater than 5 µg/dL and update the screening value used when/if the CDC reference value is updated in the future. We understand that the WIC program began referring children with BLLs above 5 µg/dL for confirmation testing during March 2013. The results of the confirmation testing should be included in the blood lead database to ensure that appropriate follow up occurs.

2. Re-initiate blood lead testing procedures that produce reliable results at a detection limit of 1 µg/dL or lower. BLLs in Butte are now low enough that trends in BLLs cannot be discerned using testing procedures with higher detection limits. The ability to characterize the trends is needed to continue to track the effectiveness of the RMAP.

3. Improve procedures for electronic data collection and maintenance to facilitate increased tracking and follow-up of individuals over time who have confirmed BLLs exceeding the CDC reference value. Documented procedures and instructions are needed to ensure consistency over time and with staff changes. Consistency will support better tracking and follow up.

4. To the extent possible, build upon community interactions via the RMAP to further promote exposure reduction education and outreach, including exposure reduction related to non-Superfund sources (e.g., house paint). It is crucial that outreach efforts be maintained at a consistently high level because the population of concern continues to change as children grow and as families move into the community.

5. Continue to seek opportunities to promote community participation in the RMAP, particularly among residents of Uptown where increased exposures and risk factors are evident. We understand that some "information fatigue" may be occurring in Butte, but continued efforts are needed to reach new residents and longer term residents who may have changed circumstances.

6. Improve the consistency with which complete blood lead records are collected, regardless of blood lead testing referral source (i.e., RMAP vs. WIC vs. pediatrician). Currently, blood lead records are only consistently compiled from RMAP and the WIC program, with other records being added on an ad hoc basis. A program to ensure that records are also obtained regularly from all doctors and clinics would provide a more robust view of BLLs in Butte and would facilitate tracking of children tested multiple times.

7. To the extent legally possible, consider collection of additional information from blood lead tested individuals that will improve interpretation of community BLL trends going forward (e.g., race, maternal education, household income level). Due to the strong correlation of some of these factors on BLLs, interpretation of differences in BLLs was limited by the lack of child-specific information on factors such as poverty levels and race. Maternal education is another factor known to be correlated with BLLs that we were not able to examine in this study. A review of relevant factors and evaluation of the feasibility of collecting additional socio-economic and demographic information should be considered.

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